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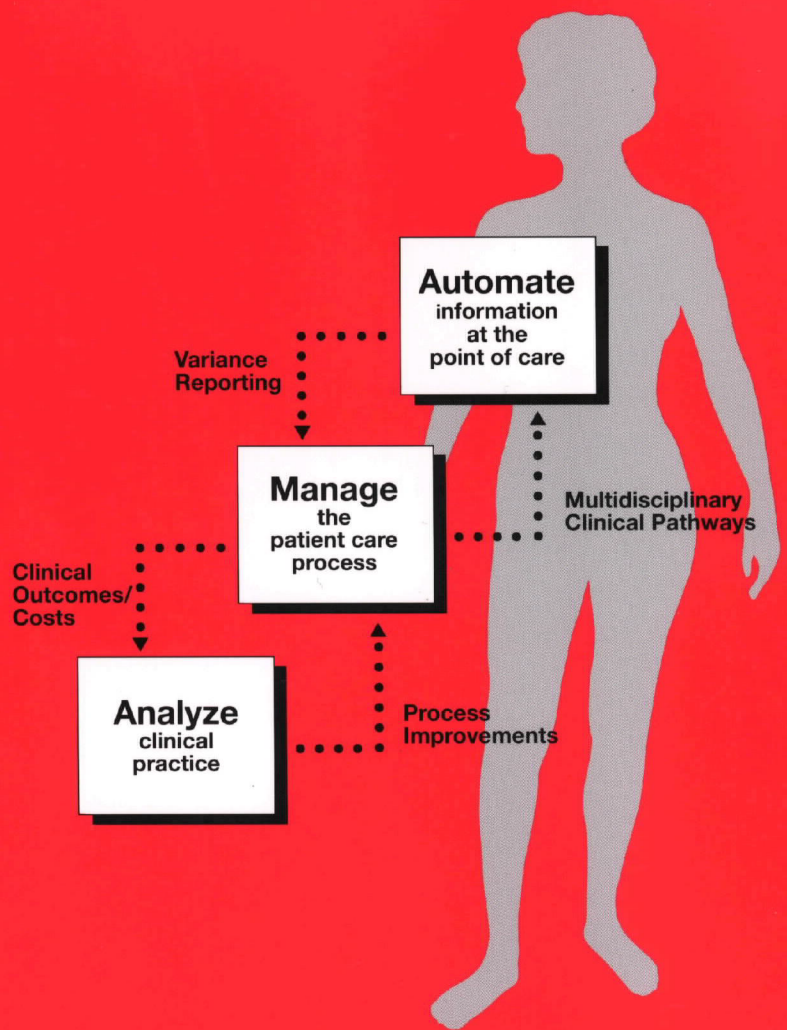
CLINICAL INFORMATION AND TECHNOLOGY SERIES

CLINICAL INFORMATION SYSTEMS

VOLUME 1: HOSPITAL-BASED SYSTEMS



CLINICAL INFORMATION SYSTEMS

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TABLE OF CONTENTS

INTRODUCTION

by: Marion J. Ball, EdD and Judith V. Douglas, MHS

Clinical Information Systems

Clinical information systems (CIS) are changing the way that healthcare is delivered, whether in the hospital, the clinic, the provider's office, or the patient's home. With capabilities ranging from advanced instrumentation to high-level decision support, CIS offer clinicians information when, where, and how they need it. Increasingly, CIS applications function as the mechanisms for delivering patient-centered care and for supporting the move towards the computer-based patient record (CPR).

These activities are the focus of the evolving discipline known as clinical informatics. In abstract terms, clinical informatics is the point at which healthcare and information science intersect. Like all abstractions, however, this definition lacks vitality and substance that we can grasp. We must master the concept if we are to master the realities that rule in the complex world of patients and clinicians.

As informaticians, we must also tackle a set of fundamental questions, questions which healthcare providers are (or should be) asking. Why is clinical informatics important? Why should they take note of this new concept and its applications? What value does clinical informatics provide in a rapidly changing, increasingly networked environment?

Chief Information Officer (CIO) Perspective

In search of insights, in June 1996, we put two open ended questions to six members of the College of Health Information Management Executives (CHIME), five of them chief information officers (CIOs) at leading institutions and the sixth a foundation representative to the CHIME Board. We asked them, first, to identify the three most important general issues they currently face as CIOs, and, second, to state three clinical informatics issues they are now addressing in their individual institutions.

Re-engineering and cultural change figured in the responses of five of the six respondents; two made specific mention of the rapid rate of change. Four of the six respondents cited the need to align information systems strategy with corporate goals and business plans; four identified the need for technical support for re-designed / re-engineering environments. Three of the six made explicit mention of integrated delivery systems (IDSs), cost and resource allocation, and physician involvement. Two respondents identified a need for changes in the work process to support automation, with one specifying the need for "automation of the clinical process for efficiency and quality."

Their responses to the second question (i.e., what issues are they addressing) were diverse, reflecting the diversity of the institutions they serve and the status of CIS at those institutions. Of the six respondents, three explicitly mentioned the move toward the computer-based patient record (CPR), and two focused on clinical data without mention of the CPR by name.

The complete lists provided by individual respondents reveal the focus within their institutions at the time we made our informal survey. For example, one CIO's list included the following issues: handling the movement to the CPR; integrating voice, data, image, and video; and migrating legacy systems. A second CIO focusing on the CPR cited satisfying the needs of individual clinical departments which emphasize uniqueness rather than commonness; selecting a vendor solution to lead the institution toward a CPR; and delivering the return on investment which the chief financial officer expects technology to provide in support of the move toward the CPR. The third CIO to explicitly

mention the CPR included the development of the CPR along with the lack of physician on-line entry and a third issue, an upcoming pilot of a new disease management system for cancer patients.

Two CIOs focused on data. The first listed the following issues: master patient identifier; clinical repository and retrospective analysis; capture of clinical data outside hospital services; clinical guidelines and decision support systems at the point of service. The second cited access to concurrent prospective qualitative clinical data, using technology to cleanse clinical data in compliance with standards, and acquiring/integrating non-inpatient clinical data.

Academic Healthcare Informatician Viewpoint

The six respondents we surveyed spoke as, or on behalf of, CIOs. For yet another view of clinical informatics, we turned to academia, where medical informaticians are both defining their discipline and educating the professionals who will practice in the coming century. What issues do they see as key in healthcare informatics? As viewed by Reinhold Haux [Aims and tasks of medical informatics, International Journal of Biomedical Computing, ed. Arie Hasman, in press], the focus will be on the health of the individual patient. Haux does not underestimate technical concerns, but deliberately relegates them to the role of prerequisites. The essential aims are what Haux terms "grand challenges"—and they are all clinical in nature. They are as follows:

Aim 1: Diagnostics: the visible body
Aim 2: Therapy: medical intervention with as little strain on the patient as possible
Aim 3: Therapy simulation
Aim 4: Early recognition and prevention
Aim 5: Compensating physical handicaps
Aim 6: Health consulting: the informed patient
Aim 7: Health reporting
Aim 8: Healthcare information systems
Aim 9: Medical documentation
Aim 10: Comprehensive documentation of medical knowledge and knowledge-based decision support

Haux's vision for medical informatics is far-reaching and will no doubt elicit the discussion it merits. Our purpose in outlining it here is simple. His vision meshes with the vision we hold for clinical informatics [MJ Ball, Comments on Reinhold Haux's Aims and tasks of medical informatics, International Journal of Biomedical Computing, ed. Arie Hasman, in press]. It reaches across disciplines and professions. It focuses on the uses of technology, not on the technology itself. It serves the health of the individual patient and of the population as a whole.

Clinical Information Systems (CIS): Hospital-Based Systems

The contributors to this series on CIS include academicians and consultants as well as clinicians. Each brings different insights to bear upon clinical informatics. Together they offer the knowledge they have gained working with hospital-based systems, managing clinical information outside of hospitals, or addressing technology issues.

This first volume on Hospital-Based Systems reflects the extensive development and evolution within this traditional sector. In a rapidly changing environment, hospitals remain valuable repositories of experience and key players on the newly constituted healthcare team.

Margaret Semancik outlines the history of hospital information systems (HIS) and their evolution toward CIS and the computer-based patient record. Kathryn J. Hannah and Ed Hammond revisit some of these same issues and carry them forward into the newly emerging healthcare environment, offering the Canadian experience as a model for healthcare delivery networks. Barbara Hoehn and Marion Ball describe clinical informatics as a patient-centric approach characterized by the integration of clinical processes and information vehicles.

Becky Clarke discusses the enabling technologies which make CIS available when, where, and how they are needed, with special attention to technology for data integration. Thomas East joins with Richard Sailors to examine CIS in critical care, addressing issues key to the CPR such as intuitive interfaces, security and confidentiality, and decision support. Specialty care, central to hospital-based services, is the focus of two additional contributions. Maxwell Weingarten and Deborah Larson explore the use of CIS prior to, during, and immediately following surgery; Vivian West and Ed Naumann evaluate CIS in emergency departments. Both of these high-cost, information-intensive areas stand to gain from a clinical informatics approach. Two chapters examine how automation can positively affect and shape the care process.

Debra Anne Slye reviews critical pathways, and Victor Friedman looks at CIS and multidisciplinary collaboration.

The CIS Imperative

In sum, the issues addressed by the contributors to this volume echo the activities described by CIOs practicing in our leading institutions and the aims set forth by medical informaticians in academia educating professionals for the next century. This echo, we believe, is validation of the importance of the clinical informatics concept.

We applaud the contributors for sharing their expertise and experiences with others. By helping to define and to implement CIS, their work will help shape healthcare in the 21st century.

Footnote on CIOs responding to the survey

We wish to express our thanks to the following individuals for their insights.

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1.0 THE HISTORY OF CLINICAL INFORMATION SYSTEMS: LEGACY SYSTEMS, COMPUTER-BASED PATIENT RECORD AND POINT OF CARE

by: Margaret Semancik

The history of computing, from a purely technical sense, is relatively short. It was not until the 1940s that several analog computers were utilized throughout the world. These early computers were used primarily for mathematical calculations and had little utilization in the healthcare arena. By the late 1960s and early 1970s, computerization began to slowly infiltrate healthcare. However, most of these early healthcare applications focused on patient accounting and general accounting functionality.

This chapter provides an overview of the history of clinical information systems, the context of clinical information systems within hospital information systems and the relationship of clinical systems to legacy systems with a look at the expectations for the future.

1.1 *Clinical Information Systems: A Definition*

To date, the definition of clinical information systems remains illusive. The term clinical information system is defined differently from organization to organization. In the broadest sense, the clinical information system is a collection of software programs and associated hardware which supports the entry, retrieval, update and analysis of patient care information and associated clinical information related to patient care. Clinical information systems are primarily those computer systems which are used to provide clinical information for the care of a patient.

There are generally two categorizations of clinical information systems. The first category is a patient-focused or a patient-centered system. This category includes automation which supports patient care processes. Applications include order entry, results reporting, clinical documentation, care planning and clinical pathways. Over time, clinical data repositories and clinical decision support systems have been added to this category.

The second category of clinical information systems is that of departmental systems. Departmental systems evolved to meet the operational needs of a particular clinical department. This category includes departmental systems for laboratory, radiology, pharmacy, medical records, staffing/scheduling, patient acuity, etc. These systems were originally designed to automate manual processes and to save clinician time. Early systems were often designed to be stand-alone to meet the needs of a particular department. Over time, the departmental systems have become closely integrated with the patient-centered clinical systems.

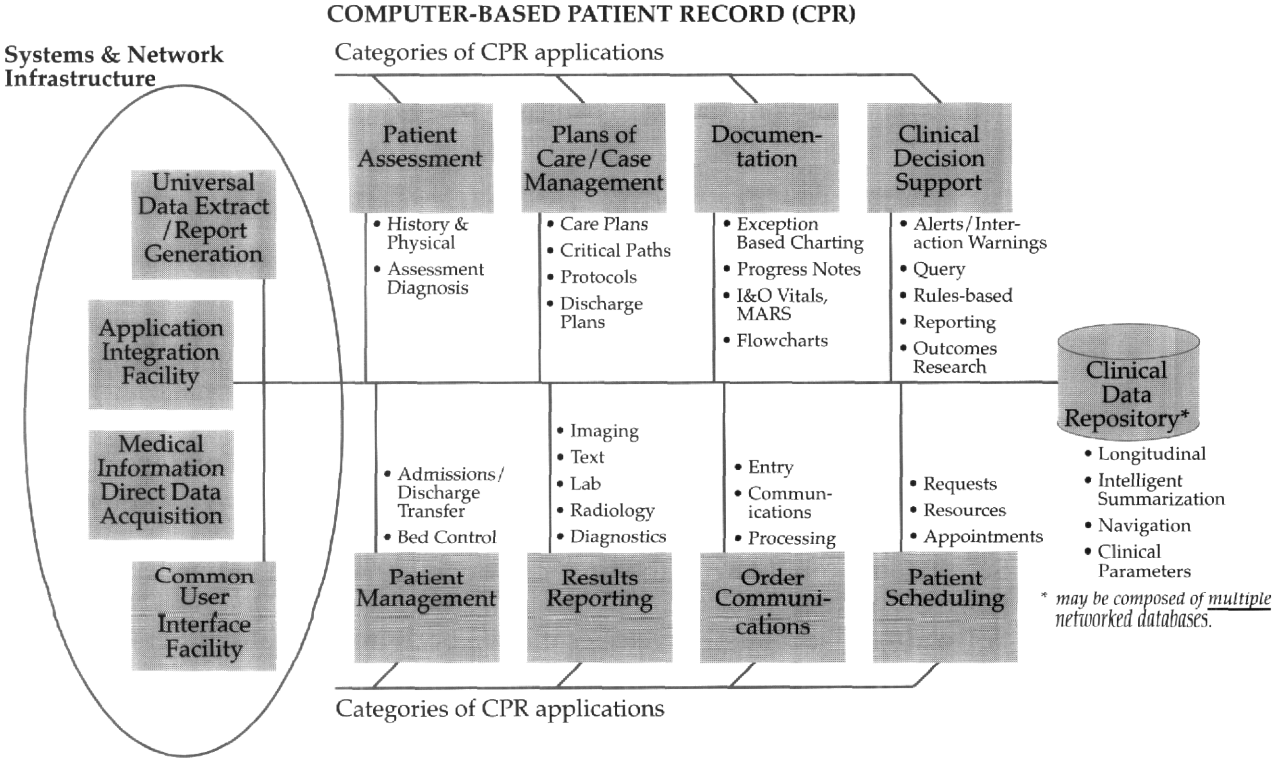
1.2 Computer-based Patient Record (CPR)

Early clinical information systems did not address the need for long-term storage of clinical data. The emergence of clinical data repositories occurred as computer technology costs and data storage costs became more manageable for healthcare organizations. The ability to store large volumes of clinical data has been the impetus for the emerging dominance of the CPR.

Clinical information systems are the data systems that make up the CPR. It is imperative to note that clinical information systems and the computer-based patient record are not synonymous terms. The CPR is a knowledge tool, not a "data" system. CPRs exist because of the clinical information systems which are creating, synthesizing and displaying the clinical data.

The Computer-based Patient Record Institute has defined the CPR as: "a collection of health information for one patient linked by a patient identifier. This information may include data, text, voice, images and video." Illustrated below is a conceptual view of the computer-based patient record.

Figure 1.1 – Computer-based Patient Record (CPR).



As illustrated, there are several major components of the computer-based patient record: Systems and Network Infrastructure, CPR Applications and a Clinical Data Repository. The CPR Applications are the feeder systems to the overall patient record. These applications include Patient Management, Patient Scheduling, Order Communications, Laboratory, and a number of other transaction-based systems. Included in the application portfolio are the systems that enable clinical decision support: alerts and interactions, queries and decision rules. Clinicians will benefit most from systems which can facilitate complex clinical decision making.

The Systems and Network Infrastructure component of the CPR essentially supports the basic technical infrastructure necessary for the development and maintenance of the CPR. The basic elements within the infrastructure include the technology for data integration and data movement - including local and wide area networks; interface engines or integration tools to move data seamlessly between applications; methods to acquire data - through device interfaces and/or direct data entry; and the common user interface facility or the data display and access methodology. Point of care devices have emerged in the marketplace to address the clinicians' need to enter and retrieve data at the point of care.

As integrated delivery systems have moved to the forefront of healthcare, the need to integrate data throughout the enterprise has become a complex issue. Moving data across disparate systems and achieving data standardization are a challenge as organizations are required to act as one system.

The Clinical Data Repository is the vehicle for long-term data storage. The repository stores longitudinal data, summarizes data in an intelligent fashion and facilitates data standardization. The growth of clinical data repositories has enabled clinicians to focus on outcomes tracking and reporting, fostered the development of clinical guidelines, and has contributed to clinical research activities.

1.3 Hospital Information Systems: A Definition

It is important to note the difference between clinical information systems and hospital information systems. Hospital information systems (HIS) encompass more than clinical, financial and administrative software applications. The term HIS is often used broadly to refer to any and all of the computerization within a hospital setting. Hospital information systems consist of the following:

1. Network infrastructure within the hospital environment.
2. Hardware to support the information system, both the main computer hardware and the peripheral devices (terminals, printers, etc.).
3. Software required to run the financial operations - both patient accounting and general accounting.
4. Software for administrative operations - both from a patient perspective and a business perspective.
5. Software for patient care management or clinical information systems.

The clinical information systems, both patient-centered systems and departmental systems, are components of the overall hospital information system. With the emergence of integrated delivery systems, individual hospital information systems will become subsets of the overall enterprise-wide information systems.

1.4 Clinical Information Systems: A History

The introduction of computerization to healthcare organizations followed on the heels of automation in banking, government and general industry. However, healthcare automation moved slowly for several reasons: most early applications were not appropriate for hospital functions; few hospitals could afford to purchase the mainframe computers; and there was a limited number of personnel who were versed in computers and who understood the unique requirements of the healthcare environment. Once computerization moved into healthcare, the logical starting point was in the patient accounting and general financial departments. Consequently, clinical automation lagged behind the financial applications.

The history of clinical information systems is presented, starting with the 1950s and moving into the present state of clinical information automation. A summary of the evolution of clinical systems is depicted below:

Table 1.1 – Evolution of clinical information systems.

Time	Industry Trends	Applications
1970s	• Charge capture • Financial focus • Streamline billing • Enhance collections	Order entry - patient charges Order communications - limited Early clinical documentation Early lab and pharmacy systems
1980s	• Changing reimbursement - focus on DRG's • Nursing shortage • Competitive environment • Focus on productivity	Early bedside systems Limited imaging Patient acuity Care planning
1990s	• Total quality management • Re-engineering • Clinical decision support • Health systems - hospital consolidation	Portable devices Clinical decision support Clinical data repositories Clinical workstation

1.4.1 The 1950s

In the 1950s, several hospitals had installed computers and had begun to develop software applications. Computer manufacturers such as IBM, had an interest in evaluating the feasibility of developing software for healthcare. In 1958-1959, John Diebold and Associates undertook a feasibility study for hospital computing at Baylor University Medical Center. The final report identified two hospital needs for automation: 1) business and financial applications and 2) medical applications.

Despite this early feasibility study, little development occurred for clinical information systems in the 1950s and well into the 1960s.

1.4.2 The 1960s

In the 1960s, there was only a small amount of computing available in the healthcare market. Most hospital information system development was driven by financial needs. During this decade, the focus was on collecting patient demographics and charge data for patient bills. Government programs such as the Tax Equity and Financial Recovery Act (TEFRA) and Medicare drove the demand for this information. For the first time, revenue and volume statistics were required for the purchase of new capital equipment. This need for information was the impetus behind the emergence of several HIS vendors.

This was the era of large mainframe computers, which were cost prohibitive to most healthcare organizations. The high cost of computing resulted in the advent of shared computer systems. Honeywell and IBM were the first two hardware vendors to develop and market financial applications for a shared hospital data processing center.

The information system development focus at this time was on automation of manual processes. Naturally the target areas were patient accounting and general accounting. Minimal amounts of clinical data were collected along with the required accounting and demographic data. At the same time, an attempt was made to develop the first order communication system. This system was geared to communicating the order information to ancillary departments and to creating a charge for the order. These first systems met with minimal success.

No true patient-centered clinical information systems were in place. A few departmental clinical systems such as laboratory systems were in their infancy. Most of the hospitals who experimented with the early clinical systems were large teaching institutions with access to federal funding or other research grants.

1.4.3 The 1970s

Early in this decade, shared services for hospital information systems became prevalent. The majority of applications developed in the 70s were financial in nature, focusing on revenue and charge capture. Consequently, the clinical applications which were developed during this time focused on order communication, order charging and limited documentation. The systems were built around charges and procedures and not the clinical data needs of physicians and clinicians.

In June 1971, the National Center for Health Services Research selected El Camino Hospital in Mountain View, CA, to demonstrate and evaluate the Technicon Medical Information Management System which had been under development for five years. The system installed at El Camino was the first widespread implementation of a clinical information system. In addition to SMS and Technicon, Datacare was another early clinical information systems vendor.

It was during this period that mainframe computers began to have competition from minicomputers. The emergence of minicomputers and local area networks allowed computer processing at reasonable costs. This technology facilitated the development of departmental systems such as laboratory and medical records. These departments were obvious areas for automation, as they had intense manual processes as well as large volumes of numeric data. In addition, patient communication systems for orders and results continued to evolve. Still, patient-centered clinical information systems were scarce. However, the technology advances made during this decade would propel clinical information systems development during the 1980s.

1.4.4 The 1980s

In the 1980s, a monumental shift in hospital economics occurred, moving the goal of healthcare providers from revenue maximization to reimbursement maximization with a focus on coordination of care and reduction in length of stay. This factor, combined with the development of microcomputers, fostered extensive automation development in the healthcare setting. Minicomputer-based hospital information systems rapidly increased, while clinical information systems development was still limited and lagged as hospital information system vendors moved from mainframe computers to minicomputers and re-tooled their financial systems. However, the minicomputer hardware platform did drive the development of clinical systems for departmental solutions such as: patient acuity; staffing and scheduling; care planning; critical care; laboratory; pharmacy; radiology; emergency room; and a number of other systems.

Despite the limitations in patient-centered clinical systems, clinicians were able to use patient care information systems for clinical documentation and care planning as well as order communications. Data entry occurred with light pens, touch screens, and limited voice recognition. During this time, early benefits realization studies were conducted, demonstrating the cost savings from implementing bedside terminals for capture and display of clinical information.

1.4.5 The 1990s

The preceding developments, as well as the evolution and mass production of technology itself, engendered the rapid expansion of clinical information systems. Technology advances such as portable personal computing, high speed networks, database development and intelligent systems have revolutionized clinical information systems.

The demands for clinical data repositories, integrated clinical information systems and decision support tools have challenged information system vendors to build and develop comprehensive tools to operationalize technology. The functionality of clini-

cal information systems accelerated rapidly as a result of this demand and technological advances.

A multiplicity of systems evolved, including decision rules, expert systems, home health, pharmacy dispensing, telemedicine, and even clinical data on the Internet. Physicians began to play a major role in the evaluation and selection of clinical information systems. The demand to transmit clinical data remotely to physician offices, rural clinics, and even to other countries has resulted in major advances in telemedicine and portable computing.

The changes in the 1990s have been dramatic, with a shift in focus year to year. In 1990 the goal was clinical information systems that would improve the quality of care. This resulted in many stand-alone clinical documentation and care planning systems. Critical path automation became a key requirement; however, available functionality was limited. In addition, organizations were looking for departmental system integration linking the stand-alone departmental systems to the HIS.

In 1991, the emphasis on clinically focused interfaces continued. Increased awareness of the technological feasibility of a CPR began to occur. Many HIS vendors began to further expand their patient-centered clinical information system functionality.

In 1992, many organizations began to view patient-centered clinical information systems as tools to contain costs and to aid in the reduction in the length of stay. The vendors were challenged to provide clinical and financial data integration.

By 1993, the push for clinical integration accelerated. Critical clinical information system requirements focused on clinical data repositories, case management functionality, clinical decision support and outcomes management.

By 1995, the healthcare industry shifted its focus from departmental integration within hospitals to enterprise-wide integration across disparate healthcare environments. As more hospitals became part of a larger health network, the integration demands increased. Organizations were looking for ways to automate outcomes management, track preventive health data and capture and store data across the continuum of care.

The information demands from the evolving integrated delivery systems have pushed the development of computer-based patient records. Organizations have begun to realize that clinical integration can only be achieved through effective management of clinical resources and that the access, analysis and evaluation of clinical information is critical for success. As illustrated earlier, the CPR provides a mechanism for clinical integration, linking disparate information sources and facilitating clinical decision making.

1.5 The Future

With the evolution of managed care and the industry shift to integrated delivery systems, clinical information systems are emerging as the enterprise-wide system integrator. Both departmental clinical information systems and patient-centered clinical information systems include the essential components of the CPR. The CPR is viewed as the key integration tool in the integrated delivery system.

Vendors will continue to be challenged to develop the clinical information systems needed in the rapidly changing healthcare environment. During the rest of the

decade and into the 21st century, technology advances will dramatically alter the way clinical information is captured, stored, retrieved and reported.

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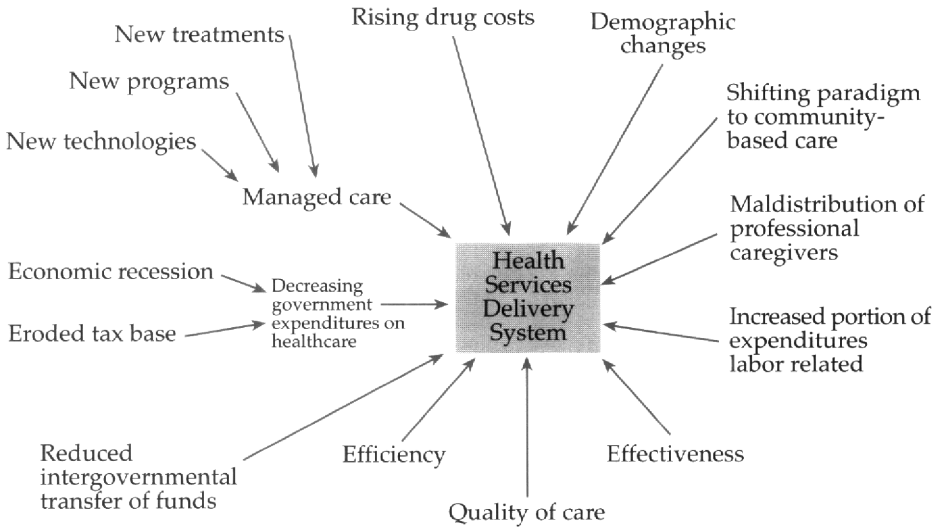
2.0 THE EVOLUTION OF CLINICAL INFORMATION SYSTEMS

by: Kathryn J. Hannah, RN, PhD & W. Ed Hammond, PhD

2.1 Information and Healthcare: Components of the Managerial Process

Healthcare organizations and health services delivery systems internationally are under enormous pressure from all sides, as shown in Figure 2.1.

Figure 2.1 – Pressures on national healthcare systems.



Overall, funding available for health services delivery has been on a steady decline. Today's healthcare environment is characterized by an explosion in new treatment modalities and newer technologies accompanied by a growth in demand for better healthcare service. The increasing average age of the population has put additional strain on the healthcare delivery system. The concurrent shift in the health services delivery paradigm from acute care to community-based care[2], demands efficient, effective and quality care.

For reasons stated above, the healthcare delivery system is under enormous pressure to change. However, decisions about healthcare organizations and healthcare delivery systems must not be based on opinion, emotion, historical precedent, or political expediency. Data and information are essential to rational decision making and good management of the health services delivery system in any country. The restructuring of health systems worldwide must be based on data and information.

Health services, healthcare delivery systems, and health organizations around the world are undergoing reorganization and reengineering. Historically, the field of medical informatics has emphasized physician delivered patient care in hospitals. Much less attention has been directed towards population-based healthcare. Increasingly, the field is beginning to emphasize health informatics which has a broader multidisciplinary focus on health services delivery including community needs assessment, population health status indicators, health promotion, and disease prevention in addition to the treatment of illness. Health informatics can and should play a major role in the reengineering and restructuring that is occurring in many healthcare organizations and health services delivery systems. Much of the data presently available is inadequate for these tasks. Therefore, current data must be transformed, and

future information requirements anticipated in order to support the reengineering of healthcare enterprises and organizations. Essential concepts are:

- Reconceptualization of health services delivery within a jurisdiction as one enterprise.
- Use of information engineering techniques.
- Development of a comprehensive information management strategy.
- Need for applying information management principles.
- Organizational implications of information management.
- Conceptual model for achieving added value as a byproduct from health service delivery data.

Enterprise health information systems can be conceived of as tools intended for use by legislators, policy makers, managers, and care givers within the health system in order to fulfill their responsibilities with regard to the delivery of health services to the population. The responsibilities related to operating a health services delivery system that is a comprehensive health services enterprise within a jurisdiction (community, state/provincial, or national) can be summarized into the following functional categories:

- Assess the health status of the population.
- Set health goals and objectives.
- Set strategic directions.
- Provide programs and services.
- Communicate with stakeholders.
- Manage resources.
- Evaluate the health services delivery system.

Such a comprehensive health services delivery enterprise requires a health information system that is defined in the broadest and most inclusive fashion possible. It should include the data and the most rudimentary media for gathering the data (e.g., pencil and paper) as well as all possible means of storing, processing, aggregating and presenting the information. A jurisdictional health information system also should include the people who interface with the system, specifically those who generate the data (i.e., the recipients of care and the care givers) and all those who use the data in its various forms (i.e., care givers, health systems managers, policy makers and legislators), as well as those who maintain the data and the means by which it is captured, stored, processed, aggregated, and presented (i.e., data gatherers, filing clerks, forms analysts, data entry clerks, computer operators, network managers).

The decision making process faced by health services enterprise managers today is far more complex compared to what prevailed in the past[3]. Some examples and reasons for this include:

- Patient-focused rather than discipline-focused care. The concept of multidisciplinary teams is increasingly being used within healthcare delivery resulting in data that focus on the recipient of care rather than the provider of care.

- Multidisciplinary and cross sectional system. Previously, decisions within the healthcare delivery system have been focused within specific service sectors (acute care, public health, mental health, long-term care, insured services) but now are becoming focused within jurisdictions (community, state/provincial, or national geographical areas) which require a cross sectoral perspective.
- Enterprise-wide system. Decisions affecting the entire health services enterprise require information about the entire health services enterprise.
- Awareness of interdependencies. Decisions affecting even a part of the health services enterprise still require information about other parts of the health services enterprise because of the impact of interdependencies among the sectors. For example, early discharge programs in the acute care sector have a major impact on the home care delivery sector.
- Outcomes-based care. Deciding to reduce expenditures on health services while maintaining the quality and maximizing the benefits to the health of citizens will require information about the outcomes of health services. There is a need to know whether or not what is done for, with or to a patient makes any difference in the health status of that individual.[8]

Re-engineering and restructuring processes among healthcare service providers have placed varying demands for information products among healthcare decision makers.[3] These include:

- Residents: Information about the health needs and health status of the population, their families, and communities.
- Recipients: Information about residents receiving services from the health services enterprise.
- Providers: Information about available persons and organizations with health service skills (health workforce).
- Services: Information about the range of health-affecting interventions and activities available in the health system.
- Programs: Information about the objectives, target recipients/populations, resource allocation, and bundling of particular sets of services.
- Resources: Distribution of fiscal (financial), physical (facilities and equipment), human (people working within the health services enterprise), and information resources.
- Utilization: Use of resources by service provider (who is providing the services), by service recipient (who is receiving the services), by program, and by type of service.

The role of the health professional (e.g., physician, nurse, dentist, physiotherapist) in managing information in healthcare facilities is of necessity related to the role of the care giver within the organization. While managers are responsible for administering the organization, care givers are usually charged with managing patient care. In most healthcare delivery facilities, it is necessary to manage both the patient care and the environment in which that care is given.

Therefore, for some time the care giver has generally been expected to provide the information necessary for managing not only patient care but also the organization (e.g., resource allocation and utilization, personnel management, planning and policy

making, decision support). This dual responsibility has generated an increasing burden on care givers to provide information because of the redundancy and duplication of information that they are expected to provide.

Healthcare delivery is information intensive. Care givers handle enormous volumes of patient care information. In fact, care givers constantly process information mentally, manually, and electronically. In every aspect of patient care, care givers are continually engaged in problem solving, using clinical judgment and decision making (e.g., assessing, identifying patient problems and diagnoses, determining appropriate action or interventions, evaluating, reassessing, and communicating). Care providers integrate information from many diverse sources throughout the organization to provide patient care and to coordinate the patient's contact with the health system. They manage patient care information for the purpose of providing care to patients.

Similarly, managing information for the purpose of administering the health enterprise across a jurisdiction is influenced by the role of the managers within the enterprise and its constituent organizations. That role, in turn, is influenced by the care delivery methodology in individual healthcare organizations that comprise the health services enterprise. Variations in decision making, patient assignment, documentation protocols, and institutional governance style all affect information management for administrative purposes. Care delivery methodologies vary widely among healthcare delivery organizations and indeed among healthcare enterprises. Some of the variables among healthcare delivery methodologies include organizational governance, resource allocation and utilization, patient classification and workload measurement systems, patient assignment methodology, information handling methodology, documentation method, type of patient database, and patient population. However, the single most important variable that determines the healthcare delivery methodology within a healthcare organization, and consequently the role of information management for administrative purposes, is the governance model in use in the organization and the healthcare delivery enterprise that governs it.

A wide range of governance models for healthcare delivery organizations and enterprises are currently in use. Ranging from capitalistic profit-driven systems to socialized welfare-motivated systems, through highly centralized and bureaucratic governance models to decentralized, shared governance models and everything in between. The role of the care givers in organizational governance and decision making will define the role and responsibility of the information management system to support these decision making processes. New models for healthcare delivery such as the regionalized healthcare delivery enterprises existing in the United Kingdom, South Africa, and some Canadian provinces and the managed care system in existence within the United States have expanded healthcare beyond the walls of the hospital. This has required an integrated health services delivery enterprise that involves the hospital, extended care facilities, the community, public health, and a multidisciplinary team of care givers (e.g., physicians, nurses, physiotherapists, nutritionists, social workers, etc.).

This new vision encompasses the concept of the electronic health record or computer-based patient record which is patient centered and includes all data relating to a person's health or well being as well as the documentation of illness care. The evolution under way is from healthcare systems which only treat people when they are ill, to health enterprises which support people's activities to protect, promote, and

maintain their own health in addition to treating people's illnesses. All of these changes require an altered approach to information management.

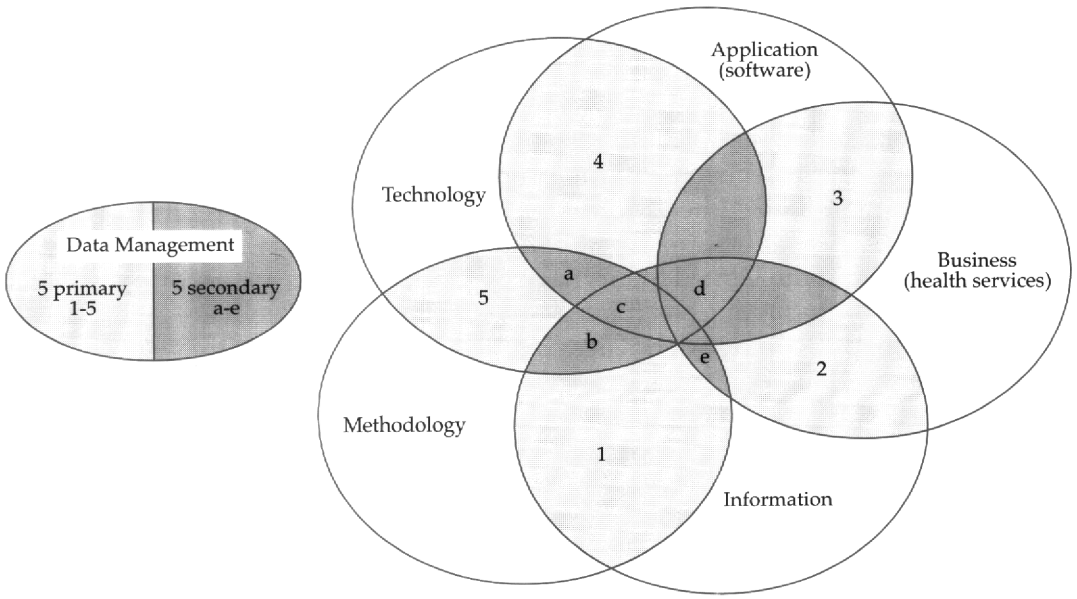
Future jurisdictional health information systems need to take into account the fundamental reason for the existence of a healthcare delivery system - to provide health services to its citizens. Thus, administrative and managerial information for use in operating the healthcare delivery enterprise should be a byproduct of the care delivery process. In the future, information about health facilities and healthcare delivery systems for use in enterprise planning and policies as well as resource allocation and utilization will need to be much more widely available to professional care providers than in the past.

2.2 Management of Information Resources

Data and information are essential to rational decision making and good management of the health services delivery enterprise in any country. The restructuring and ongoing management of health systems worldwide are impacted by these concepts. The information systems necessary to provide data and information can be characterized by a number of interdependent domains. Data management is central because data provide the binding principle: Applications are processing data; technology is transferring data; and methodology is identifying how data are captured and where they are used in order to minimize the cost of data as a resource.

The whole purpose is to serve the business of delivering health services. As shown in Figure 2.2, each domain is interdependent with the others; at the intersections between the domains there is an interdependency.

Figure 2.2 – The scope of data management in terms of the relationships among information systems domains.



However, data management must consider all domains. Focus on any one domain could in effect create an imbalance in the system thereby exposing the health services enterprise (the business) to an unnecessary risk. Data management involves the intersection of all the interdependent domains.

Data management is complex due to the inherent complexity and dynamic nature of the data sources. Definition of data is continually changing. Development of new technologies and applications has dissolved barriers of time and space.

Data management includes identifying and facilitating standard data definitions and the corresponding data capture processes. Data can be transformed into information by selecting, collating, aggregating, and presenting pertinent data. Quality of data is thus critical for deriving meaningful information. Data is a collection of facts which when captured within a specific context can be deemed as information. Data management can be considered the management of the connections between data and the context in which they are captured. Data management must be done in a coordinated way, by qualified information management specialists, in order to maximize the value of the data and minimize the cost of data capture.

Integrated information systems require new management processes to ensure that data is of sufficient quality, is adequately secure, is used for the purposes agreed to, and is disposed of appropriately when no longer required. The more data is used for productive purposes, the more its value increases in terms of unit cost of capture. Data standards ensure comparability across many diverse sources and enhance administrative processes, accountability measures, service provider information exchange, and security provisions. A minimum set of standard data also ensures that information providers are not burdened by redundant data requests.

The importance of data management will grow with changes in healthcare delivery modalities and growth in technology. The ability and agility to respond to these changes can give a healthcare service enterprise a distinct competitive advantage. Organizations can respond by way of changes in capacity, capability and flexibility of service offerings. A right balance of useful resources can help an enterprise to deliver optimum care.

2.3 Informatics in Health System Management: The Alberta Experience

The concepts discussed in the first part of this chapter consider health systems from the broadest possible perspective (i.e., encompassing all of the health determinants influencing the wellness of all citizens of a jurisdiction, be it national, state, or local). The case study used to illustrate the principles discussed is one that provides universal access to health services. Although not the model currently in place in the United States, this model is operational in a large number of countries. Its principles can be applied in the United States and other countries having other models for their health services delivery system. Readers are advised to select elements that best apply to their situations.

Healthcare is a provincial responsibility in Canada, not a federal one. Consequently, there are ten provincial healthcare systems in Canada rather than a single federal system.[4] Until April 1994, the healthcare system in Alberta was typical of other provincial healthcare systems in Canada. The provincial Department of Health

had responsibility for funding and monitoring the provincial health services delivery system. There were five sectors or "stovepipes" within the Alberta healthcare delivery system: the practitioner sector (e.g., physicians, dentists); the acute care sector; the long-term care sector; the public health sector; and the mental health sector. Each of the five existed in splendid solitude. There was little communication among them, they were funded separately and each was governed by its own legislation. Within each of the five sectors, there were multiple users, each with its own applications, systems, and databases. Users of the healthcare delivery system worked in discrete multiple database systems.

Between 1993 and 1995, the Alberta healthcare delivery system underwent a transformation. Initially, the values of the citizens were considered; existing legislation and policy regarding the delivery of health services were reviewed; programs delivered by service providers were studied; and the resources available to the government to address the health status of the population were assessed. Based on analysis and interpretation of extensive public input, the Minister redesigned the healthcare system in Alberta. Now, rather than a health system comprised of five separate province-wide sectors (practitioner, acute care, long-term care, public health, and mental health), there are 17 health regions. Within each of these geographical boundaries there is a regional health authority that initially has responsibility for acute care, long-term care, and public health services to all citizens residing within that boundary. Eventually, regional health authorities are expected to have responsibility for all health services within their respective boundaries. Citizens are entitled to healthcare by virtue of residence.[5]

2.4 Health Information Processing Strategy

In anticipation of the need to support the reorganization of the healthcare delivery system in Alberta, a project was begun to develop a Health Information Processing Strategy (HIPS) for Alberta. This project used information engineering principles and enterprise computing concepts to undertake a detailed business process analysis and redesign. This culminated in a detailed functional model of the health system in Alberta. From this model, three architectures were developed: a data/information architecture, an application architecture, and a technical architecture.[6,7]

The information architecture uses the service event as its fundamental unit of construction.[8] A service event is comprised of the services delivered by a service provider to a service recipient at a particular location at a specific time with an associated cost. The primary key for organizing health data is the service recipient.

The application architecture is the intersection of the data with the business processes. It is comprised of an infrastructure base, a set of repository databases, operational applications, evaluation applications, and a set of executive corporate applications.

The technical architecture is based on principles of interoperability, portability, scalability, expandability, and connectivity. The concept in the technical architecture is that the applications and databases are available through a communications network to a variety of different delivery hardware units. Each of those pieces of hardware has a communications function, a processing function, and data storage

capability. The capacity for each of these activities varies depending on whether it is a personal workstation, a work group server, a central facility, or an external resource.[6]

The province does not have the resources to discard its legacy systems. It was not possible to throw out either the existing systems or the data that they contained. Rather, HIPS principles were applied to all new systems development and acquisitions. However, in the interim, a data warehouse concept was developed to link administrative records and use a metadata repository to map data from legacy systems.[3] This approach enabled the use of existing administrative data from legacy systems. The process differed from that reported by Williams, Mehr, and Fries[9] only in the volume of records linked; the Alberta experience required the linkage of approximately 2.5 million individual records from six different legacy systems. Like other jurisdictions, Alberta had a great deal of data and very little information.

Managing a healthcare delivery system in these transitional times requires tough decisions by all stakeholders–the citizens who are the recipients of care, care providers, the bureaucracy, and the politicians. Fundamental to these decisions is the means by which existing data and information could be managed to provide the greatest benefit to the health system at the least cost.

The objective of information management in the Alberta experience was to facilitate the development of the "feedback loops" necessary to monitor the dynamic interaction of the components comprising a restructured health system. The use of standard data and data standards permits the creation of longitudinal cross sectoral multidisciplinary person-specific health records. The focus is on the individual receiving the care rather than the organization or health discipline delivering that care. Standardized data captured at the point of service can be used by individual service providers, service delivery organizations, regions, and government and third party insurers to optimize service delivery.

2.5 Hospital Information Systems

A hospital is a sub-enterprise of a jurisdictional health services delivery enterprise. The management of information in the hospital setting and its environs is a critical component in the process of healthcare delivery. The problem has been further complicated by an exponential increase in the amount of data to be managed, in the number of stakeholders in the process, and in the real-time requirements. In the United States, 12-15% of the cost of healthcare is attributed to the costs associated with information handling.[10] The cost of information handling in the hospital setting has led to the use of computers in an attempt to provide more data at lower costs.

Early applications dealt with administration and financial matters. Later applications included task-oriented functions such as Admission/Discharge/Transfer (ADT), order entry, and result reporting. With the availability of minicomputers, various departmental service-related systems such as laboratory, radiology, and pharmacy were developed. Few, if any, of these systems were electronically connected. Development of hospital information systems was a factor of technology (hardware and software), people (developer and user), and economics. Jackson estimates the costs of information handling to vary between 25% and 39% of the total cost of healthcare.[11] Most health informatics professionals agree that a reasonable cost for the electronic information handling is at least 2% to 3% of the operational budget for an institution.

A critical aspect of the Hospital Information System (HIS) is the availability of complete, accurate, and timely data at the point of care. This is justified by the observations that a point of care approach can eliminate redundant tests, eliminate the need to reestablish diagnoses, increase awareness of drug allergies and adverse events, increase awareness of the medications the patient is taking, and enhance communication among healthcare providers.

Modern healthcare institutions generate massive volumes of data that must be collected, transmitted, recorded, retrieved, and summarized. Managing these tasks for achieving clinical relevancy could be difficult. Computer-based Hospital Information Systems were thus designed and implemented to serve this purpose, i.e., to provide a computer-based framework for facilitating information exchange within a health service enterprise.

Current Hospital Information Systems grew out of developmental work that took place during the 1970s. Functional specifications, system design, and technology selection were driven by the immediate problem at hand. Systems were designed to deal primarily with the problem of moving transaction-oriented data throughout the institution. The types of functions which were developed included ADT, order entry / result reporting, and charge or cost capture.

In most cases, the systems were controlled by administrative and financial personnel who had responsibility for the accounting systems. Interaction between healthcare providers and the HIS was, with a few exceptions, limited to batch printed reports such as cumulative laboratory summaries and nursing care plans. Mainframe technology was utilized as the best hardware platform for providing an extensive network. Gradually, Hospital Information Systems evolved into communication networks linking terminals and output devices in key patient care or service areas to a central processing unit that coordinates all essential patient care activities. Thus, the HIS provides a communication system between departments (e.g., dietary, nursing units, pharmacy, laboratory); a central information system for receipt, sorting, transmission, storage, and retrieval of information; and a high speed data processing system for fast and economic processing of data to provide information.

Hospital information systems currently in use can be broadly categorized into two kinds depending on its application. Individual departments often utilize a dedicated information system that serves a specific clinical information management need for the department. Examples of this include systems designed for laboratory, radiology, surgery, anesthesia, and pharmacy.

The second type of information system used in hospitals is the one that manages non-clinical patient data, such as demographics, billing and other administrative functions. By interlinking various discrete information systems by means of appropriate computer networking components, an integrated information management system can be formulated.

The main functions of a typical HIS are:

- Recognize both sending and receiving stations.
- Format all messages and manage all of the message routing (message switching).
- Validate, check, and edit each message to assure its quality.
- Control all of the hardware and software needed to perform the first three functions.

- Assemble transaction data and communicate with the accounting system.

The differences among non-clinical systems are primarily in the complexity of integration technology. Some systems have more sophisticated provisions for validating, checking, editing, formatting, and documentation than others. Some respond faster and offer a better variety of displays. These variations are differences in the communication and presentation aspects of the system. Other systems provide more complex integration of the application structure and data retention, for example, total integration of information from the lab, radiology, pharmacy, medical records interacting with the nursing stations providing communication from order entry to result reports.

Another difference among Hospital Information Systems is the orientation towards the data content: some systems are oriented around the financial and administrative data, while others are organized around the patient care data. In the latter case, administrative and financial data and functions are derived from the patient care information. More patient information, such as history, physical and progress data, is contained in these systems because their emphasis is integration of direct clinical information.

As indicated previously, commercial Hospital Information Systems currently available are built primarily around the framework of technologies, design philosophies, and healthcare delivery models of the 1970s. As new concepts and new technologies have become available, these classic systems are being modified, most usually on a superficial level, to accommodate these changes. Most of these systems were designed with no thought of an electronic patient record and certainly no concept of a longitudinal cross sectoral, multidisciplinary, patient-specific record. In fact, most systems maintain patient specific data for a single hospitalization event and usually retain the information for only a few months after the patient is discharged. These systems use a mainframe computer, a central database, and character-based terminals. Few of these systems support a unified patient problem list and complete integrated studies and therapy data sets. Current systems are primarily an automation of the manual system for healthcare delivery. The design philosophy reflects the flow of documents as the primary communication. The traditional paper chart still exists in even the most computerized hospitals today. No major systems exist today in which all data and the management of that data are fully computerized.

2.5.1 Administrative and Financial Modules

Accounts receivable, accounts payable, general ledger, materials management, payroll, and human resources applications are the minimum management functions required of the administrative and financial modules of an HIS. Accounts receivable at a minimum consists of charge capture for the transmission to another system. Other functions include utilization review; professional and technical component billing; proration of revenue; corrections and late charges; adjustments and payments; account aging by method of payment, by category of patient and category of physician, by date of encounter, by inpatient/outpatient and by date of payment; and collections, including delinquent accounts report, collection comments, dunning letters, turnover letters, and collection agency reports. Miscellaneous software applications

are required to support other management functions such as environment and energy control, marketing, fund raising, and public relations.

Departmental management functions include inventory control of supplies, drugs, and perishables; item tracking of such things as specimens, charts, and films; revenue and utilization statistics; word processing; electronic mail; budget and actual monthly financial statements for use in variance analysis; workload analysis and personnel scheduling; human resources and payroll.

2.5.1.1 ADT Modules

The ADT module is the core of any hospital information system. At a minimum, this module must establish a patient record, provide a unique encounter identification number, and document the place of encounter. Other functions include bed availability; call lists; scheduling; collection of demographic data, referral data, and reason for admission; precertification; verification of benefit plan and ability to pay; pre-admission orders and pre-surgery preparation procedures.

The admission process includes updating of pre-admit/appointment data; creating the hospital account number; collecting the admitting diagnosis; initiating concurrent review; notifying dietary, housekeeping and human services; collecting/initiating orders; notification of orders/requisitions; bed assignment; notification of arrival to all interested parties; census with locators by patient name, identification number, account number, nursing station, physician group (includes primary, admitting, referring, and consultants); organize work flow by data to be reviewed, reports to be completed, and reports to be verified/signed; bed control; room charging including variable services/room and multiple patients/day; concurrent review including utilization, quality assurance and risk management; transfer of patients including bed control and discontinue orders; pending discharge, including notification of next admission, prepare discharge medications and contact home health provider; discharge, including verify diagnoses and procedures, discharge summary, patient instruction and return appointments; and case abstracting, including diagnosis/procedure coding, diagnosis related group statistics and retrospective review.

2.5.1.2 Order Entry Module

The Order Entry Module handles data collection, usually at the point of care or at terminals located in the patient care area. Orders for specific medications and treatment can be transmitted through the computer system for immediate implementation.

Order entry is a function common to almost all service departments in the hospital. At a minimum, orders may be entered in a batch mode as a method of charge capture. The full functionality includes initial order capture of procedure, urgency, frequency, scheduling (begin date and time and duration), performer, ordering physician and comments; order verification; order sets; activation of preorders; check for inappropriate orders including frequency by patient, match to diagnosis, negated by medications and credential verification; order follow up including look up patient by requisition number, list overdue pending orders and continuing orders due to expire; initiate work, including insertion on work-to-be-done list by service department and

nursing station, print requisition, queue for scheduling, and print labels; and enter charge if billing on order entry.

An important capacity of the order entry system can be the ability to provide a validation check for users. At the University of Tokyo Hospital, for example, when a physician prescribes an inappropriate dosage, the system provides a warning. The system also has the ability to alert physicians when they order too many clinical tests without sufficient justification. This feature is critical for a teaching hospital utilizing many young physicians in training programs. The education and training of physicians is a very important function of the hospital. Interns and resident physicians who often lack professional self confidence tend to order more clinical tests than are necessary. Excessive tests could also strain the hospital's financial resources. The warning alert on the order entry system had remarkable effects, and the number of clinical tests ordered decreased approximately 30% following system implementation. The warning system was evaluated by interviewing the users: all agreed that the system gave them a chance to reconsider the necessity of the clinical tests, which had some educational value.

2.5.1.3 Result Reporting Module

Result reporting requirements vary markedly among departments. Minimum result reporting consists of notification that a procedure is complete. Other functionality includes: cancel procedure; entry of result including flag process complete and bill; enter normal/abnormal range (numeric, coded or text); check data for accuracy through edit tables and internal consistency such as delta checks; and report result including immediate result reporting, flow sheets or graph, related calculated results and physician prompts.

2.5.1.4 Scheduling

Scheduling of admissions, surgery, outpatient encounters, and diagnostics is critical for the smooth, integrated working of the healthcare facility. The outpatient scheduling permits the preadmission ordering of tests and preoperative diagnostic assessments and coordination of the performance of those tests and assessments with the admission. Effective management of the mix of patients and length of time for encounters is facilitated by a good scheduling system. Patient notification of pending appointments reduces no-show rates.

2.5.2 Specialized Support for Clinical Functions

Software application programs are required to provide specialized support for departmental services. Some examples, by department, are listed below:

- Clinical laboratory - Tasks include accession numbering, collection list, specimen tracking, specimen logging, automatic capture of results from instruments, quality control, processing controls, calculation of mean and standard deviation for a test, analysis of patient trend, technologist verification, check for drug/test interactions, and protocols.

- Radiology - Tasks include result reporting (preliminary, final, amended), electronic signature, reference file, and images of various types.
- Pharmacy - Tasks include verification of order by pharmacist, dual result reporting by pharmacy (number dispensed) and by nurse (number administered), unit dose tracking (fills and returns), IV admixture, and chemotherapy protocols.
- Nursing systems - Tasks include nursing assessment, nursing diagnoses, nursing interventions, care plans, medication administration records, nursing workload, and nursing notes of patient outcomes.
- Medical records - Requirements include a list of all diagnoses, an encounter-oriented summary abstract, time-oriented summaries (flow sheets), utilization review, and longitudinal studies.
- Dietary - Tasks include meal planning, menu selection, food distribution, inventory, ordering, nutrition management, and drug/food interactions.
- Consultation programs - Capabilities include bibliographic retrieval, calculations, modeling, decision support systems, protocols, and health knowledge bases such as the Physician's Desk Reference (PDR), emergency procedures, and Poison Index.
- Critical care - Special needs include electronic data capture for patient monitoring and charting.
- Patient support - Capabilities include security, privacy, confidentiality for patient data, information sheets for patient education and awareness, concern for the general patient welfare, reminders of appointments, admissions, tests, and health maintenance reminders.

2.6 Beyond the Traditional Hospital Management Information System: Enterprise-Wide Information Systems

An integrated information system is critical for the new model of healthcare delivery systems. The integration of information can only be realized by developing an electronic health record. Requirements for developing such a system include a physical network to support such integration, an infrastructure to manage and regulate such a structure, standards for data interchange, a common data model defining the objects to be transmitted, and a common clinical vocabulary. Future systems must reflect a major paradigm shift in health services delivery models. The underlying philosophy must be patient centered.

In developing new systems much of the functionality of current systems will still have to be retained. Processing of orders, reporting of results, ADT, scheduling, department service management, supply replacement, inventory, materials management, and documentation will still be the key components. Quality assurance should occur in real-time, rather than recognizing days later that something was overlooked or that a mistake was made.

At an International Medical Informatics Association (IMIA) Working Group 10 workshop on Hospital Information Systems in 1988, Collen stated that the goal of a hospital information system should be to "use computers and communications equipment to collect, store, process, retrieve, and communicate relative patient care and administrative information for all activities and functions within the hospital, its

outpatient medical offices, its clinical support services (clinical laboratories, radiology, pharmacy, intensive care unit, etc.), and with its affiliated facilities. Such an integrated, multi-facility, information system should have the capability for communication and integration of all patient data during the patient's service lifetime, from all of the information subsystems and all facilities in the medical system complex; and to provide administrative and clinical decision support."[12] This statement is important because it recognizes that clinical information is not the property of a single facility but rather is part of a global resource which focuses on the patient centered record.

The term Hospital Information System (HIS) is limited in what it encompasses and envisions for the future. A more encompassing term is the Electronic Health Record (EHR) or Computer-based Patient Record System (CPRS) which includes not only hospital functionality but also features a comprehensive integrated delivery system. However, it must be recognized that these terms do not incorporate the use of aggregated health data for the management of the health services delivery system (i.e., assessing population health status, setting health goals and objectives, defining strategic directions, program planning and delivery, and resource allocation).

Health service enterprises also need to exploit technological advances because of the networks which have become available. Now, the system is the network and the network is the system. Networks are enablers which allow health service enterprises to be virtual organizations. Until recently, the various communication barriers imposed by distance and time made concrete physical organizations essential and dictated management structures partitioned to allow each individual geographical facility to be managed independently. Today, management of virtual health enterprises is possible because the technology ties the various component health facilities together with communication networks. Distance, time, and location become almost irrelevant.

A patient-centered record requires that all data relating to the patient and the patient's well being must be available at all times and accessible at appropriate locations. Data from all relevant sources must be integrated into a single record including but not limited to demographic data, data related to health determinants and risk factors, along with diagnostic and treatment data from all contacts with the health enterprise (e.g., primary care providers; all members of the multidisciplinary healthcare team; home care; public or private acute care, long-term care, or mental health facilities). This record will likely take the form of a virtual record and may well be stored in a variety of locations. A common problem list, a complete drug profile, and patient allergies should be centrally stored, maintained and accessible. Data must be readily shared among all the providers of care. The patient record must be a lifetime record, extending from before birth to after death.

The new HIS will contain character-based data, image data, waveforms, drawings, digital pictures, motion videos, voice and sound recordings. The networks tying these systems together must have a wide bandwidth in order to accommodate the volume of data which must be exchanged in real time among facilities. Electronic mail could provide easy linkage among the providers requesting consults and discussing a patient's care. A clinically rich common medical and health vocabulary whose major purpose is communication needs to be created and used by all stakeholders. Confidentiality and privacy issues must be adequately supported with patient consent for the sharing of data.

The new systems must support source data capture, most specifically by primary care providers (e.g., midwives, nurses, physicians, dentists, acupuncturists, traditional care givers, psychologists, and social workers). Ideally, decision support systems would also be available at or near the point of care. Most computer support algorithms are useful only if they are interactive with the person making the clinical decision at the time of decision making. Workstations customized for physicians, nurses, and other clinical care givers as well as administrators and researchers will be mandatory for tomorrow's systems. The move toward managed care increases the necessity for informed, algorithmic-driven order sets. Decision support systems, operating in the background, will save much money as well as improve patient care. As an example, a typical physician session involving ordering tests and prescribing treatment may typically invoke several thousand decision rules. These decision rules need to be standardized and shared by the international community.

2.7 A Hospital Management Information System: Enterprise-Wide Information Systems

Medivision is a product created by a unique Canadian joint venture that is introducing new operational paradigms to Canadian hospitals. In the mid 1980s, information management problems and increasing budgetary constraints began to threaten the effectiveness and financial accountability of hospitals. Five Quebec hospitals banded together to seek an innovative approach; the main goal was to maintain quality patient care under conditions of intense economic retrenchment.

The five hospitals enlisted the IST Group, a leading Canadian provider of software to healthcare, and the DMR Group Inc., a computer consulting firm. The joint venture was founded in 1989 and the first release of this paradigm breaking project was called SIDOCI. Subsequently, the product has been continually refined and developed. IST has now assumed majority ownership of the product which has been renamed Medivision.

Medivision is a multidisciplinary, patient centered clinical information system designed to integrate all relevant patient data, originating from both healthcare providers and existing department systems. This product goes beyond computerizing the paper patient chart by incorporating documents such as the care plan and work sheets into the electronic record. The patient is registered in the existing patient index and registration systems which are interfaced with Medivision. All clinical activities, notes, orders, and results are recorded in and processed through the Medivision patient record. Orders and requests are not a separate module. Orders are placed for specific patients within their unique personal file. Data capture is facilitated through responses to queries, touchscreen technology and a Windows-based graphical user interface (GUI).

When healthcare professionals enter the Medivision system, they are identified by their professional role (e.g., physician, nurse, laboratory technician) and their personal patient list appears. They have access to those parts of the patient record and those transactions (prescriptions, nursing orders, test results) allowed by their security clearance. The security clearance is defined by each healthcare enterprise and can vary from one organization to another within the enterprise.

All orders and requests are sent to the appropriate professionals or ancillary systems on-line from the relevant Medivision patient record. Results from systems (e.g., laboratory, diagnostic imaging, pharmacy, and dietary) are returned to Medivision. The patient records containing new results are flagged to notify healthcare professionals of new information as they log in to Medivision. Data capture is simplified by providing point and click choices for the series of queries and responses within the Medivision patient record. Healthcare professionals can build their own personalized profiles for data capture and personalized intervention menu based on Medivision's extensive natural language clinical dictionary. Healthcare enterprises can also generate an approved set of clinical protocols or care maps.

All clinical data are stored in an on-line database or data warehouse containing clinical and financial data structured in accordance with standard international nomenclatures. This warehouse allows analysis of the abstracted and summarized patient encounter information to be used for resource allocation, management, quality assurance, utilization review, teaching of students in the health professions, and policy making.

Medivision provides an example that embodies the principles of a longitudinal, multidisciplinary, cross sectoral, and person-specific electronic health record. It is based on open systems and client server architectural constructs, international data standards, intuitive human interface, and multiple data format input. This product is representative of the new generation of enterprise-wide health information systems becoming available on the commercial market. No doubt there will be an increasing number of such systems available internationally.

2.8 Conclusion

Countries around the globe are searching for ways to simultaneously improve the delivery of healthcare and reduce the costs connected with providing this care. The ultimate goal of sustaining and improving the health status of the population of a local, state, national, or even international community purportedly guides all such efforts. An interesting phenomenon surrounding the changes being undertaken in a number of healthcare systems emerges when cursory comparisons of various attempts are made. Various countries demonstrate remarkable differences in approach, sometimes even the adoption of strategies which seem to move their healthcare systems in opposite directions. Certainly, the health reform initiatives within the British National Health Services, Canadian Provincial Healthcare Systems, and the United States provide striking examples of these differences. Yet these initiatives and many others all claim to support the improvement of healthcare and health status among their respective populations. The common goal is "Health for All."

However, if health systems are changing in different ways for the same reasons, can all the strategies for change be effective ones? How will these be evaluated? How will the outcomes of the health systems and of health services be evaluated? Previous concepts of the scope of a hospital information system must change along with changes in the healthcare process and the restructuring of national and regional health systems. The functionality presently provided by such systems merely provides a base for beginning the development of the Health Information Systems of the future. Information is key and information systems are essential to enabling and mea-

suring the efficient delivery of health services and the effectiveness of national health systems.

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3.0 CLINICAL INFORMATICS: A PATIENT-CENTRIC APPROACH

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3.1 *The Move Towards Integrated Delivery Systems*

In today's rapidly changing healthcare marketplace, healthcare providers are migrating from free standing care centers to Integrated Delivery Systems (IDS): organizational enterprises which address the needs of the healthcare population across the full continuum of care. Strategic, operational and economic foci are being redirected from supporting the segmented provision of care (such as within hospitals, critical care units and skilled nursing facilities) to coordinating, delivering, managing, evaluating and improving care and wellness services across multiple providers, numerous geographic sites and expanding time-frames (Figure 3.1).

Primary care groups are replacing hospitals as the centers of these delivery systems. Organizational structures within each healthcare provider in the network are becoming flatter, and successful Integrated Delivery Systems are transitioning from providing data processing services to becoming information-based organizations .

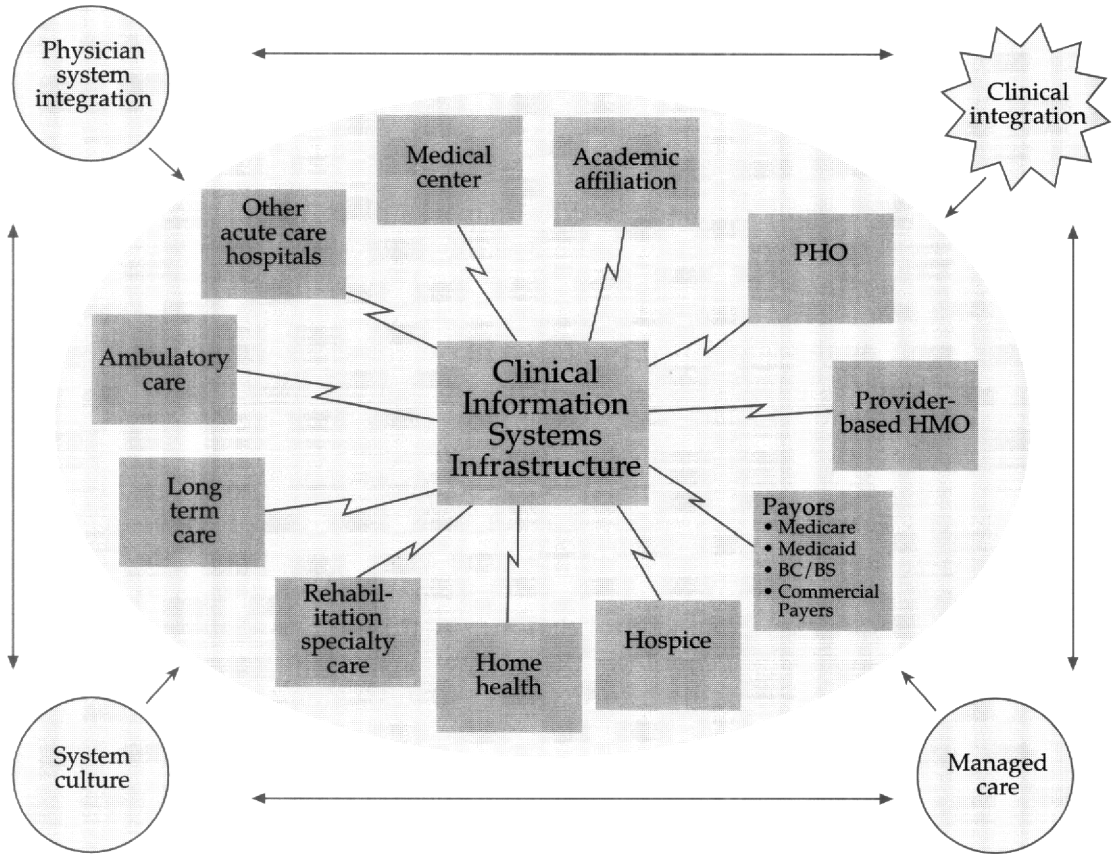
The importance of the information systems infrastructure to these Integrated Delivery Systems (the technology, the integration mechanisms, the resources and the operational processes surrounding information management) cannot be stressed enough. The ability of a healthcare organization to rapidly gather, communicate, analyze and act on network-wide information will be a critical factor in the successful development and ongoing management of these expanding care networks.

Industry trends show that the primary influencers in the development and successful deployment of an Integrated Delivery System are:

- The ability of the enterprise to act as a system rather than discrete entities vying for resources, funding and management attention,
- The degree of physician-system integration and the ability to manage the risks resulting from this relationship,
- The ability of the organization to gain and maintain covered lives in step with the pace of managed care penetration in the geographic marketplace of the IDS, and
- The level of clinical integration within each of the individual entities of the system and across the continuum of care.

While we believe that each of these initiatives is vital to the success of all healthcare providers today, clinical integration within and among the members of the healthcare continuum is paramount to both the immediate and long-term success of healthcare provider organizations in meeting the needs of their current and future healthcare service consumer base.

Figure 3.1 – Model of Integrated Delivery System (IDS).



3.2 Clinical Integration

Clinical integration is the extent to which patient care services are coordinated across the various functions, activities and operating units of an IDS to maximize the value of the services delivered to its patients and members. It can be argued that clinical integration is the key to providing seamless care across the continuum and the basis of all integrated delivery systems efforts.

Without clinical integration, an IDS would be hard pressed to understand, evaluate and manage the relationship with its physicians, identifying and partnering with the high quality, cost effective providers while separating from the high cost, high resource utilizers of services.

Without clinical integration, an IDS may very well gain covered lives but would find it difficult to evaluate its ability to successfully support and maintain those covered lives over the long term within the contracts negotiated with the managed care organizations.

And, as organizational and technological linkages expand outside the hospital into primary and ambulatory care centers, alternate care delivery sites and into the members' homes, schools and employment centers, a high degree of "systemness" becomes vital as coordinated clinical efforts broaden into the total integration of preventative and treatment services.

3.3 Clinical Challenges

As Integrated Delivery Systems look to enhance clinical integration both within and across the continuum, they will need to resolve clinical information delivery issues that are both enterprise-wide and provider-specific. Three of the key clinical information delivery challenges each IDS will need to successfully address are :

- Delivering clinical information that supports vertical integration within each care provider environment;
- Delivering clinical information that facilitates care management in a capitation environment; and
- Delivering clinical information that supports care coordination across the continuum.

These challenges raise the expectations for the benefits we hope to achieve through implementing clinical information systems beyond those historically sought. Integrated clinical information systems will need to provide common functionality across all providers while addressing the unique information and technology needs of the individual provider organizations within the system. They will need to be able to deliver critical information to all sites of care decision-making. As clinical protocols and critical path initiatives expand across the continuum, integrated clinical systems will need to provide clinical and demographic data elements needed to coordinate care within the IDS and to facilitate patient care follow-through between patient visits. They will need to support the clinical information components of acute and ambulatory health records and provide a migration path to the computer-based patient record. If we hope to achieve the kinds of benefits outlined above, we will need to address the clinical information delivery needs of the Integrated Delivery Systems within a new paradigm.

3.4 Achieving Benefits of Clinical Information Delivery

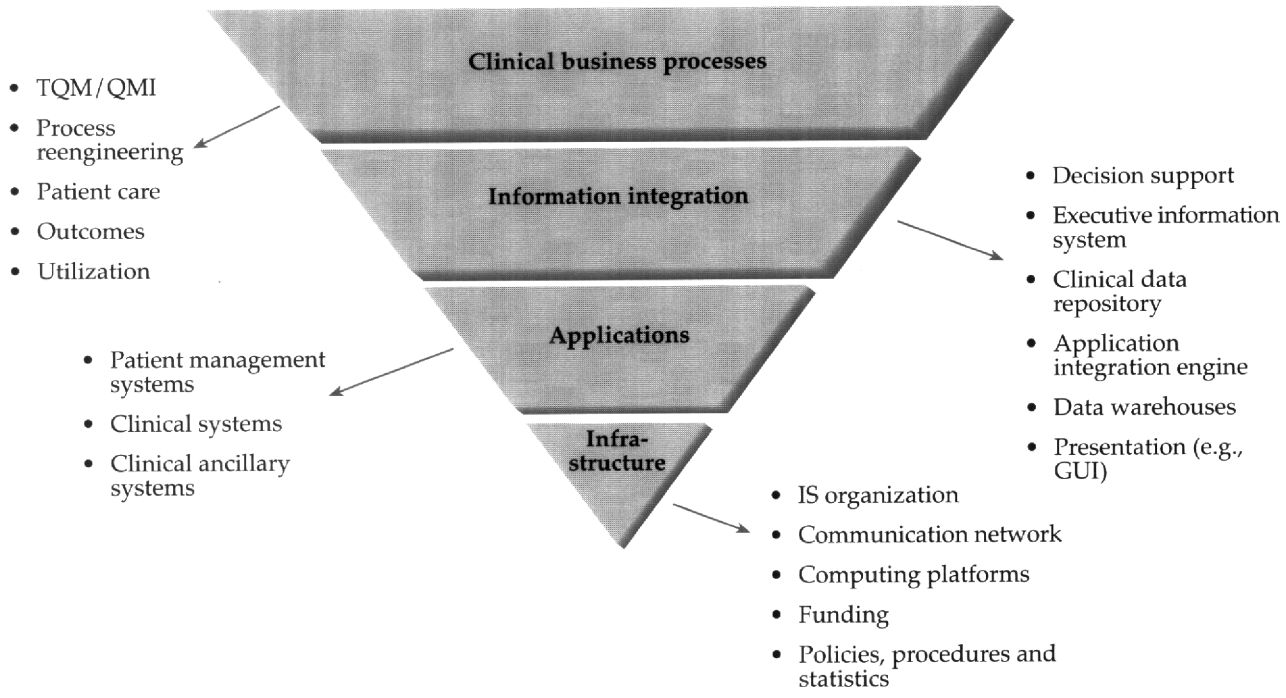
While healthcare providers have been implementing clinical information systems for the past 25 years, it has only been recently that the benefits we hope to achieve from these technologies go beyond automating manual processes. Over the past five years, we have looked towards clinical information systems to :

1. Improve the quality of care,
2. Function as tools to help manage costs,
3. Identify, measure and manage clinical outcomes, and

4. Provide clinical information in a manner not available through manual documentation thus encouraging active clinician interaction with technology.

Historically, the level of benefits realization of clinical information systems in relationship to user expectations has been less than satisfactory. This is because we often tend to look at the implementation of these systems within the traditional information delivery framework (Figure 3.2).

Figure 3.2 – Traditional information delivery model.



This approach focuses heavily on the technology components of clinical systems. Often, the most important component of the model, the clinical processes being supported, is ignored or receives only a passing interest in relationship to the other model components.

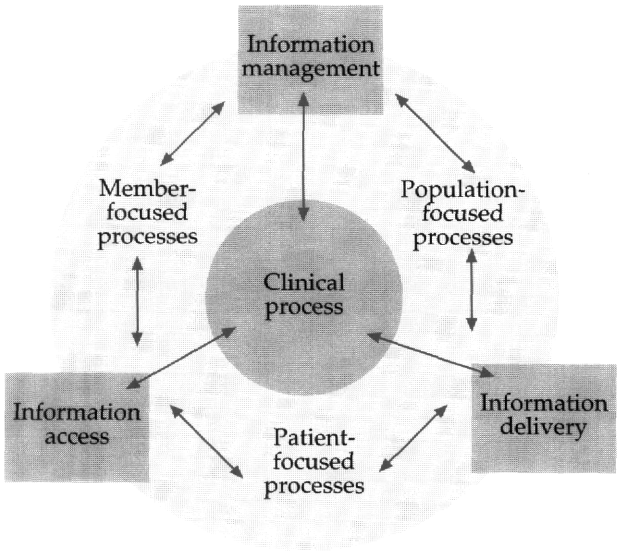
In order to attain the benefits that clinical information systems can truly provide and that healthcare organizations must achieve to insure successful clinical integration, a new approach must be instituted. The structure of this approach must be PATIENT-centric: clinical process and technology integration throughout the healthcare enterprise to meet the information needs of the clinical team. This approach is Clinical Informatics.

3.5 Clinical Informatics

A recent Internet search of Grateful Med for the term clinical informatics resulted in no matches. The healthcare industry has defined medical informatics, nursing informatics, and dental informatics - all of which focus on the information needs of specific professionals in meeting the roles and responsibilities that fall within the purview of medicine, nursing and dentistry.

We believe that clinical informatics allows us to move out of the parochial views of specific professions and support the needs of all clinical decision makers. Clinical Informatics is the integration of newly designed or redesigned clinical processes, information sciences and information technologies to meet the needs of the clinical decision makers. This model is clinical-process-centered rather than technology-centered, identifying the information access, delivery and management vehicles needed to support these clinical processes (Figure 3.3).

Figure 3.3 – Clinical information delivery model.



We believe that in the clinical setting there tend to be three major process groups that require information access, delivery and management support. These groups center on:

- Patient-focused clinical processes - those processes that address the interaction between the clinical care provider and the individual patient or client seeking services;
- Population-focused clinical processes - those processes that address the service delivery needs of specific patient populations (by diagnosis, age, geographic region) and support the clinicians defining, evaluating and disseminating best clinical practices; and

- Member-focused clinical processes - those processes that address the service needs of the covered lives that are the responsibility of the IDS and support the case managers' and clinical administrators' decision making efforts.

To support these clinical processes, we need to apply information science techniques (such as data modeling, data structures, data definitions and linkages) and information technologies (such as networks, platforms, applications and resources) to meet the information access, delivery and management needs of the clinical decision maker.

- Information access - technologies, processes, decisions, and human resources that facilitate the acquisition of data, information and knowledge by users.
- Information delivery - computer analysts and the applications they develop to present useful information to the users.
- Information management - technological tools, standards, processes and professionals that support the users in collecting, analyzing and evaluating information and knowledge to initiate change.

The following tables reflect the integration of clinical processes and information vehicles inherent in the Clinical Informatics model.

Table 3.1 – Meeting the needs of the patient and care provider.

Clinical Informatics: Meeting the Needs of the Patient & Care Provider			
Patient-Focused Clinical Processes	**Information Access**	**Information Delivery**	**Information Management**
• Identify patient/member • Schedule encounter/resource • Register/enroll patient • Verify benefits/eligibility • Obtain authorization to treat • Manage refferals • Access patient Hx • Evaluate patient condition • Diagnose • Plan care • Deliver services • Document care • Report results • Manage compliance to care	• LANs WANs • Integration engines • Point of care technology • Mobile computing • Remote access • GUI • Clinical informaticians • Unique patient indentifier • Smart cards • Patient access/input	• Rules-based orders management • Integrated results • Patient scheduling • Patient management • Clinical ancillary systems • Ambulatory records • Critical care systems • Home care systems	• Document imaging • Longitudinal patient history • Health record • Family record • Integrated data repositories • Specialty databases

Table 3.2 – Meeting the needs of the population and care evaluator.

Clinical Informatics: Meeting the Needs of the Population & Care Evaluator			
Population-Focused Clinical Processes	**Information Access**	**Information Delivery**	**Information Management**
• Develop protocols and guidelines • Monitor quality indicators • Identify and respond to protocol variances • Evaluate resource utilization and costs of care • Assess, evaluate and track outcomes • Profile providers • Provide clinical education • Expand clinical knowledge bases • Support research • Measure compliance to care	• Networks • Integration engines • Clinical thesaurus • Security plans • Computing cycles • Remote access • Natural language query • Biostatisticians • Internet access	• Clinical libraries • Knowledge databases • Cost accounting • Quality management • Critical paths • E-mail • Bulletin boards	• Statistical software • Integrated clinical and financial repositories • Outcomes management • Variance reporting

Table 3.3 – Meeting the needs of the member and care manager.

Clinical Informatics: Meeting the Needs of the Member & Care Manager			
Member-Focused Clinical Processes	**Information Access**	**Information Delivery**	**Information Management**
• Assign clinical protocols • Collect and archive clinical data • Coordinate hand-offs between providers • Monitor compliance to care • Identify and monitor at-risk populations • Manage risks and liabilities	• Networks • Integration engines • Clinical dictionaries • Case managers • Ad hoc queries	• Case management • Variance reporting • Protocol libraries • Rules-based clinical systems • Integrated scheduling • Referral management systems • Cost accounting applications • Decision support	• Longitudinal patient histories • Case mix data • Patient/member profiles • Profit/loss information • Disease management

Like the healthcare sector it serves, the Clinical Informatics model is highly complex. The clinical integration efforts that span the enterprise and their associated clinical information delivery needs often overlap with the clinical integration and information initiatives of each of the IDS entities. Therefore, a full appreciation and understanding of all clinical integration efforts must be had before a realistic application of information technology can be made available to the clinical decision makers.

Enterprise-wide clinical integration activities that will need clinical informatics support include:

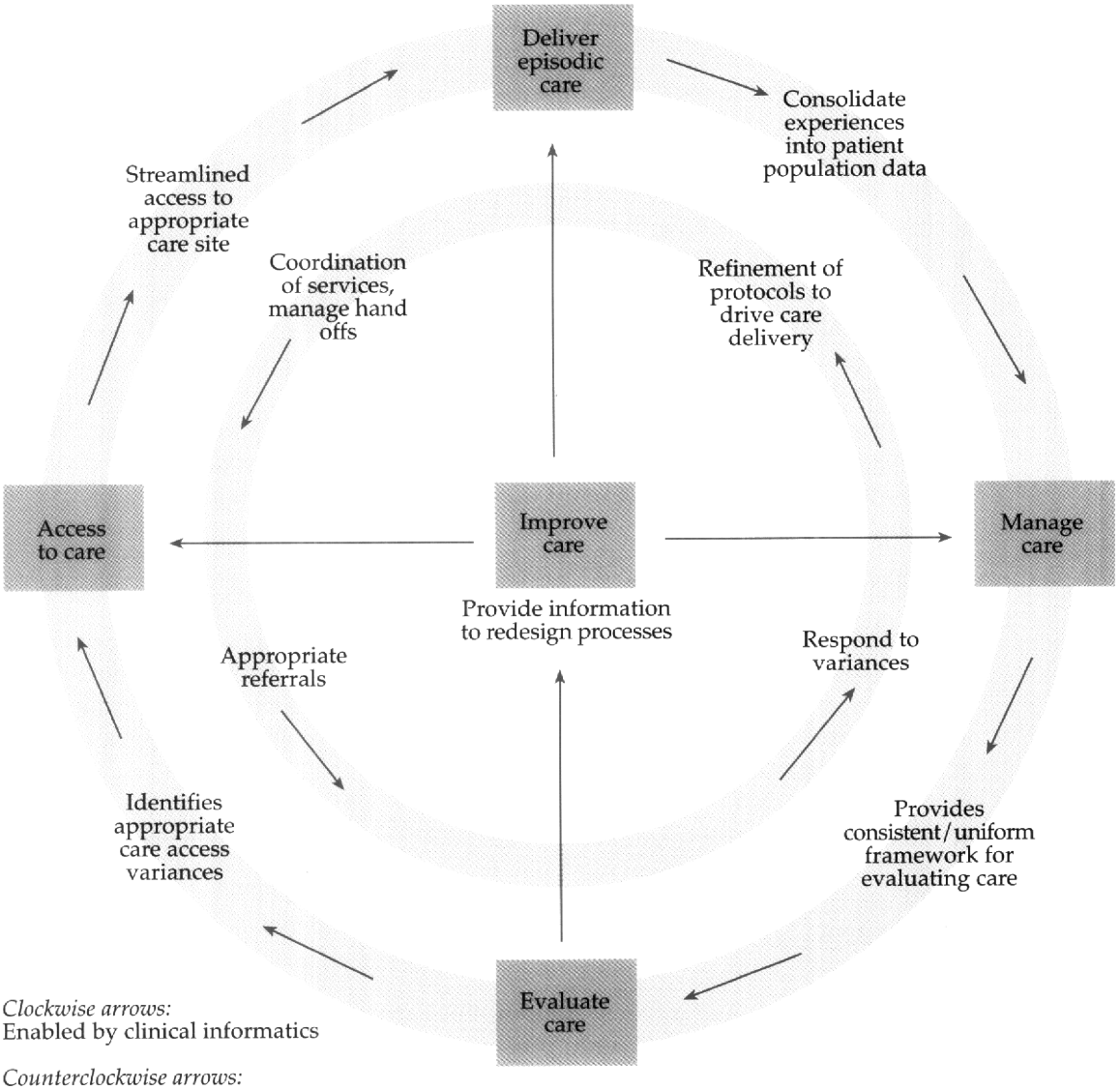
1. Enterprise-wide member enrollment/patient registration
2. Enterprise-wide unique patient identification
3. Integration of the physical medical record
4. Clinical management across the continuum
5. Enterprise-wide clinical administration
6. Costing of clinical care
7. Outcomes measurement and management
8. Functional integration of ancillary clinical departments
9. Enterprise-wide clinical planning
10. Clinical knowledge transfer and generation of the clinical knowledge base

Within each clinical entity of the IDS, clinical integration efforts are under way that will need clinical informatics support. These include efforts to:

1. Provide seamless access to care at the most appropriate site
2. Provide and manage episodic care to patients
3. Manage the care of large patient and member populations
4. Evaluate the care provided in each clinical setting, and
5. Improve care access, delivery and management based on concurrent care evaluation

By successfully applying clinical informatics principles at both the enterprise and the entity level, Integrated Delivery Systems will best position themselves to meet the clinical information needs of all clinical decision makers, will better provide clinical services to its membership, will more successfully manage the risks associated with managed care and will maximize the benefits achieved through the successful integration of clinical processes, information sciences and clinical information technologies now and in the future.

Figure 3.4 – Potential outcomes of applying clinical informatics to successfully meet clinical objectives of the IDS enterprise and entities.



4.0 INTEGRATING CLINICAL INFORMATION SYSTEMS AT THE POINT OF CARE

by: Becky Clarke

Integration is the key to unifying data from the disparate, best of breed, Clinical Information Systems (CIS) for timely access to accurate and complete information which is critical for cost-effective, quality healthcare delivery. To be effective, data integration must occur instantaneously and automatically. Technology has evolved to provide efficient means of data collection, standards to facilitate data storage and retrieval, cost-effective means of data storage, effective presentation of the information, along with a variety of options for data integration. Sophisticated departmental clinical information systems that enhance the efficiency of department operations and patient care are not new to this industry. However, currently there is not a single vendor that provides total automation for all clinical departments, thus providing a single vendor solution. This creates a critical need for effective integration of the best of breed departmental clinical information systems. Though we have seen significant advancements in technology that now offer the potential to perform and document appropriate activities at the point of care and effectively integrate all of this data, the full impact has not yet been realized. This chapter discusses both the clinical requirements supporting integration and the available technologies.

4.1 *Why Integrate Clinical Data*

Studies have shown that regardless of the discipline, documenting activities when they occur into a system designed for efficient data capture is more accurate and generates fewer errors than documentation done manually or at a later time into a central workstation.[1] The positive aspects of a CIS are seen in both the quantity and quality of the documentation, specifically:

- Creating a complete patient record with greater legibility and more consistent and concise information
- Eliminating redundant charting
- Providing simultaneous and remote access

Given the definition of a CIS at the point of care to be "the use of computers to collect, process, retrieve and effectively present current information related to patient care activities performed where the patient is"[2], the disciplines and systems are limited. Though there are many clinical departments for which sophisticated information systems exist, such as laboratory, radiology, respiratory care, dietary, pharmacy, and nursing, there are few that collate the information from all of these disciplines to provide a complete clinical status report of the patient. Without full integration of these departmental systems into the system used by the care givers along with effective presentation of the information, the full benefits of a clinical information system at the point of care will not be realized. Though there are several CISs on the market today that support documentation of nursing activities and allow for automatic integration of information from other clinical information systems, they are not widely

used throughout an organization. The primary reason for their limited use has been cost and the general resistance to automation in these areas. However, without its utilization through the entire patient stay, the continuity and usefulness of information is limited. With recent trends towards capitation and managed care, healthcare organizations are pressured to cut costs without sacrificing quality. One way to accomplish this is through deployment of a comprehensive CIS. In situations where CISs are deployed, they have improved the quantity and quality of patient care and job satisfaction by facilitating efficient patient care processes and effective documentation of patient care activities, providing timely access to accurate information and simultaneous access to treatment information. No longer are multiple healthcare workers wasting valuable time simultaneously chasing the single elusive physical chart and thumbing through it to find the desired information. CISs also facilitate the capture of information for accurate charge processing and the measurement and implementation of changes to improve patient outcomes[3], activities that both increase capture of lost revenues and decrease cost by shortening the patient's hospitalization. Because clinical information systems provide a complete and legible patient record, some insurance companies have also taken notice and offer discounted malpractice premiums to clinicians utilizing these systems in their practice. However, without complete integration of information from all clinical disciplines, these systems are limited. It is estimated that fewer than 5% of the hospitals in the United States have deployed a fully integrated clinical information system at the point of care.

Technology has evolved to facilitate activities performed at the point of care by other ancillary service areas such as respiratory care and the clinical laboratory along with several options for data integration. However, the challenges that remain are the complete automation of all clinical care areas, the integration of the appropriate data into the comprehensive CIS, and the effective presentation of this large amount and disparate types of data.

4.1.1 Clinical Information Systems for Nursing at the Point of Care

One of the biggest advantages of a CIS for nursing is the automatic capture of information from various medical devices such as ECG monitors, noninvasive and invasive hemodynamic equipment and infusion pumps. This eliminates the need to manually transcribe or include loose "strips" of supporting information in the patient's medical record, thereby resulting in fewer documentation errors. This has led to the growth in systems that can provide such automated charting processes. Other functionality provided includes[4,5]:

- Order entry
- Patient assessments such as admission, transfer and discharge
- Nursing care plans
- Kardex/work lists
- Charting and nursing notes including patient responses to treatment
- Reminders/notices
- Patient teaching guidelines
- Flow sheets documenting things such as vital signs, fluid balance, and treatments

- Discharge planning
- Case management and acuity
- Database support
- Interface support to patient-attached instruments such as physiologic and fetal monitors, ventilators, infusion pumps, etc.
- Management reporting
- Decision support
- Customization/tailoring to meet the unique needs of each clinical care area

Without the integration of information from other clinical disciplines such as the blood gas laboratory, clinical laboratory, radiology, and respiratory care the information is incomplete and does not provide a comparative picture of treatments and a timely measurement of their effects on the patient. A complete electronic integration of real time data can facilitate proper treatment of conditions such as arrhythmia, electrolyte imbalance, hyper- or hypoglycemia, cardiac arrest, and ventilator weaning. Additionally, automated integration of results significantly reduces the risk of errors associated with manual recording and communication. Recent studies reveal a 15% error rate associated with manual communication of laboratory results compared to a zero error rate associated with the automated integration of these results into a CIS.[6] Additionally, it is estimated that the amount of time required for manual communication of laboratory results within a nursing unit ranges from one to two hours. This time delay in itself could result in fragmented and inaccurate information, especially in a busy critical care setting. A couple of areas clearly missing from this list are medication and dietary charting. The interaction necessary between these disciplines and nursing can be accomplished either through a well integrated interface between standalone systems or modules that exist within the CIS. The interaction between dietary and pharmacy is necessary for both food and medication allergies, interactions, and adverse reactions. Drug complications are one of the common types of adverse hospital events experienced by patients. The ability of the system to automatically notify the healthcare provider of scheduled and overdue medications, along with a mechanism to easily verify the correct patient, time, dose, medication, and route, work to virtually eliminate medication errors.

4.1.2 Clinical Information Systems for Respiratory Care at the Point of Care

The practice of respiratory care today is changing rapidly with the reorganization of healthcare delivery. The challenge faced is that of becoming a well-integrated member of the patient care team.[7] Clinical information systems for respiratory care facilitate department management, efficient work flow, and effective documentation of direct patient care activities. These systems consist of a centralized workstation complemented with hand-held data collection units to facilitate accurate collection of information at the point of care through manual entry or electronic transfer from select ventilators. Electronic transfer of ventilator information eliminates manual recording of patient-related data, alarm settings, ventilator status as well the need for manual documentation of changes made to the ventilator setting. Other features provided by these systems include:

- Order processing
- Point of care data collection
- Work assignments
- Chart reporting
- Automatic charge capture

The challenge for respiratory care management information systems is the integration of patient related information into the CIS, the significance of which has previously been discussed.

4.1.3 Clinical Information Systems for Laboratory Services at the Point of Care

The practice of laboratory medicine is also expanding outside the centralized laboratory to the point of care. Today, analyzers exist that can perform whole blood analysis for sodium, potassium, chloride, ionized calcium, urea nitrogen, glucose, hematocrit, and blood gases at the bedside.[8] However, to define these analyzers or their data management systems as a CIS at the point of care is inappropriate, for at most they contain a history of the tests and results performed through that methodology. Whereas this provides trending for that methodology, without integration into the LIS, these results cannot be compared to others performed in the central laboratory, they are not available for use in performing complex algorithms, nor is sufficient patient information available for determining reference ranges. Though these devices can provide the care giver with results in 90 seconds from a very small amount of whole blood, the challenge for the manufacturers is the instantaneous integration of these results into the current laboratory information system. Subsequent automatic and electronic transmission to the CIS provides comparative results used to establish clinical relevance and measurements of effective treatment changes. Without timely integration, the risk of duplicate orders increases and patient care decisions are delayed, resulting in increased cost from lengthened patient stays.

4.2 Integration Technology

Data integration has two major components: the physical link and the transfer methodology. The physical connection can be made in five different ways. These are serial RS-232, Ethernet, modem, infrared, and spread spectrum radio frequency. The transfer methodologies include scripting (terminal emulation or screen scraping) and electronic data interchange (EDI). Multiple connectivity options should be deployed, utilizing the solution that best satisfies the requirements for data capture, transmission, presentation, location, and needs of the clinician. The following sections discuss these two components in further detail.

4.2.1 Physical Connectivity

Though the physical links are discussed with more technical detail in another chapter, this section briefly discusses the impact of the various connectivity options on

data integration at the point of care.

4.2.1.1 Serial Communication

A serial connection is a direct physical point-to-point link used for electronic transmission of digital information between two devices. Several national and international standards exist for defining this protocol. Without signal repeaters, this methodology has distance limitations of approximately 1000 feet. Serial transmission is capable of a range of speeds from 30 to several thousand characters per second. Though distance limitations exist, this is an appropriate and very effective method for establishing a physical connection between two stationary devices. While it can be used to connect mobile devices, communication is disrupted until the physical connection is re-established. To effectively utilize this connectivity methodology, both the sending and receiving systems must have compatible circuits and appropriate software and there must be a proper cable to connect the two systems. This methodology is used extensively throughout the healthcare delivery system to connect patient monitors to the CIS and laboratory analyzers to the Laboratory Information System (LIS). Traditionally, a serial connection is the only output option other than a printer provided on devices such as monitors and laboratory analyzers. Prior to the widespread use of networks in the healthcare setting, this method of connectivity was used extensively to connect disparate systems for either batch or real- time transfer of information. It is conceivable that a CIS used extensively throughout an acute care setting could have thousands of monitoring and other devices connected through this methodology. This methodology is still used by many information systems to also connect workstations to the host system in a non-networked computing environment.

4.2.1.2 Ethernet Communication

Ethernet is one of the earliest and least expensive network types. A network can be defined as a group of computers connected by a communications link that enables any device to interact with any other on the network. The term 'network' is used to describe an entire system of hosts, workstations, terminals and other devices. It is a way to connect individual computers so they can share resources. Ethernet network utilizes data packages to transfer data around the network. Ethernet is capable of transmitting up to a million characters per second and utilizes a Bus or Star arrangement (topology). In a bus topology, all computers on the network are connected to the main wire, commonly known as a backbone. Devices connected in this manner all have equal access to the backbone at any point in time. This is a popular connectivity methodology for linking workstations and printers to the host or file server(s). It readily supports incremental additions and the network adapters, network hubs, and cabling are all relatively inexpensive. In a star topology, devices are connected through a central hub. The central hub distributes the signals to all the connecting cables. Though this is the best configuration for overall reliability since it does not rely on the main "backbone" as in the bus topology, it is more expensive due to the cost of the hubs and the necessity for multiple hubs, since a hub supports only small configurations. Implementation of a network requires that all devices speak the same language (protocol) as the network itself. The network protocol is the logical layer

that checks for line availability, packages the data, routes the data to the receiver, and prevents collisions on the network. Some common network protocols include TCP/IP, IPX/SPX, and NetBios. Since networks require a special type of physical connection from the device, known as an adapter, this type of connectivity is used primarily for linking printers, workstations, and computers. Monitoring equipment and laboratory analyzers typically do not have this type of output. Networks aren't as physically limiting as connectivity via serial RS-232 because the nodes can be widely dispersed across buildings, cities, states, nations, or the world. This makes networks an ideal solution for connecting computers, workstations, and printers within an institution or even remotely from other institutions or physician offices. Once the concept and working module of a network was deployed, it was followed by the concept and deployment of connecting the network of networks, known as the Internet, thus linking millions of computers and providing access to vast amounts of information.

4.2.1.3 Modems

Modems make data transmission through the use of ordinary phone lines possible. A modem, short for modulator/demodulator, is a device that converts a digital stream of data to sound for transmission through phone lines and converts sound signals back into digital data (demodulator). The modem is physically attached to the computer's serial port. It is common today to find the modem as a card internal to the PC. Modem communication requires a physical device at both the sending and receiving end utilizing the same protocol. Common modem protocols are Xmodem, Ymodem, Zmodem, and Kermit, to name a few. Modems provide a means of connecting with a computer system just as any other user connected directly, thus providing real-time access to information from remote locations. Since modems utilize existing telephone systems, this type of access is even more widely available than through existing networks, though its effectiveness is limited by the quality of the phone lines, the transmission rate of the modems, and the availability of an open line at the receiving end. Modems also facilitate transmission of reports to printers or fax machines in the physician's office or alternate remote locations.

The one characteristic which Serial RS-232, Ethernet, and modems have in common is the requirement for some type of umbilical cord (physical attachment) which severely limits the ability for one to move away from the workstation and yet maintain a connection to the network with real-time access to information. Connectivity methods using infrared and radio frequency modalities offer users the option of wireless communication with the host computer, thus allowing access to information from outside the walls of an institution.

4.2.1.4 Wireless LANs

Both infrared and spread-spectrum are used in wireless local area networks (LAN). There are four components to a wireless LAN: the wireless adapter utilized at the client (hand-held or pen-based portable), the antenna that links the wireless client to the access point, an access point that physically attaches to the wired LAN, and the wired LAN. However, if a wired LAN already exists, only the access point, wireless adapters, and the antenna are required to create a wireless LAN solution. Wireless LANs

operate on a significantly narrower bandwidth than wired LANs and are therefore not truly comparable to physical connectivity. Wireless LANS can be considered a viable option in situations where a physical connection between user computer and the host computer is difficult to make or maintain. Recent improvements in performance of wireless communication facilitated by emerging standards and reduction in prices have fueled a steady rise in the use of wireless communications. It is estimated that wireless LAN sales will reach $725.4 million by the end of 1998 compared with the 1994 figure of $94.4 million. In the acute healthcare setting alone, the installed base grew an estimated 25% to 30% in 1995 over 1994.

4.2.1.5 Spread-spectrum

Spread-spectrum is a wireless connection for peer-to-peer LANs or a wireless connection to wired LANs using radio airwaves in the Industrial, Scientific, and Medical (ISM) bands of the electromagnetic spectrum. The primary goal of spread-spectrum is to avoid interference. It is offered in two varieties to accomplish this goal: direct-sequencing spread-spectrum and frequency-hopping spread-spectrum. Direct-sequencing spreads the transmission over a fixed range of the frequency bands while frequency-hopping hops between several frequencies to avoid interference.

4.2.1.6 Infrared

Though use of infrared light for communication is less costly than radio frequency technology, it cannot work through walls or support roaming since it requires a line of sight path for communication. Roaming maintains the connection as the wireless device moves between access points. Like spread-spectrum, infrared falls into two distinct areas: short-distance links connecting notebook computers to printers, and LAN links. LAN links can utilize multiple paths such as bouncing the light beam off ceilings and walls.

Wireless hand-held and other portable pen-based devices have found their way into retail stores, warehouses, manufacturing plants, and even into hospitals. In retail stores, warehouses, and manufacturing plants they are commonly used for inventory management and sales. However, in hospitals, hand-held or pen-based portables are used by respiratory therapists to collect information at the patient's bedside and either automatically upload real-time data into the Respiratory Care clinical information system via spread-spectrum radio frequency, or batch upload data at a later time via a direct serial link. These types of devices are also used for entry of specimen collection information at the patient bedside and incorporation of the data into some Laboratory Information Systems. They have been envisioned to facilitate order notification, patient validation, data collection, and automatic result transfer from point of care laboratory analyzers to their data management system and subsequently into the central LIS or other clinical information system. The ability to transfer the data is the same as previously described for the Respiratory Care clinical information system, either real-time or via batch upload at a later time. Few universal applications exist for this type of display / data entry device. Rather, these hand-held and pen-based portable devices require functions specifically designed and developed for the application and hardware due to the display areas and enhanced data entry facilities.

4.3 Integration Methodology

The previous discussion focused on the physical connectivity options among various computer devices. Following is a discussion of data transfer methodologies available in the industry today. Two transfer methodologies previously identified as electronic data interchange (EDI) and terminal emulation will be discussed.

4.3.1 Electronic Data Interchange (EDI)

The role of EDI is to provide data access through consistent communication programs between disparate systems. It eliminates manual entry and keying errors, provides consistent and simultaneous transfers to make data accessible to the care givers. This communication is enhanced by the ability to provide several layers of error handling to verify that the data sent is the same as the data received, request retransmission as needed, and provide audits of unexpected transmission occurrences. EDI incorporates industry standards for data format and communication protocol. Though standards exist, compliance is not mandatory. The American Society for Testing and Materials (ASTM) has developed a widely accepted communication and data format standard for electronic transmission of digital information between clinical laboratory instruments and computer systems such as Laboratory Information Systems. Since it is designed to specifically address the needs of clinical laboratory instruments, it does not encompass the entire scope of healthcare information. Health Level Seven (HL7), first introduced in October 1987, has become a widely accepted standard throughout the healthcare industry. It covers data communication involved in processes such as admission/discharge and transfer (ADT), orders, and financial reports. Version 2.3, released in 1996, expanded standards to include scheduling, clinical trials, immunizations, patient care, nursing care plans, and other areas such as structures for reports, envelopes for images, and automated waveforms. Version 3.0, anticipated in 1997, is designed to incorporate a message model and an object model, both using a mutual HL7 content message.

Before the proliferation of clinical information systems, a unique interface either existed or was created to connect disparate systems. For example, all clinical departments such as laboratory, radiology, nursing, and pharmacy require patient admission, discharge, and transfer (ADT) information. Historically this need was serviced through four separate interfaces, each transmitting the same information at the same time. Though this methodology still exists today, the focus is turning from creating unique interfaces to strategic deployment of an interface engine. An interface engine, a system in itself, is designed to connect multiple disparate systems within an organization through a central process without re-inventing an interface each time a module or system is added or modified. In the example presented above, the four ADT interfaces now become a single interface from the ADT system into the interface engine, thus eliminating the redundant output of information from the ADT system. However, there still exists an interface from the engine into each clinical information system.

4.3.2 Scripting

Scripting involves running lines of program codes that include user prompts and predefined data in order to make data entry operations faster and easier. Scripting provides automated entry of information into the receiving system thereby providing a consistent way of making repeated entries. This methodology has proven to be efficient and successful in stable environments such as charge posting. However, with rapid changes to the healthcare environment, there could be significant ongoing maintenance costs associated with updating and revising scripts. Examples of changes include:

- Function changes by vendor
- Function changes by customers through user-defined settings
- Changes to processes and procedures that affect the operations of the system
- Introduction of new items as they pertain to an environment (i.e., new cartridges or tests introduced by point of care laboratory analyzer manufacturers).

Scripting is functionally limited by the fact that every prompt and error or function deviation must be accounted for in the scripting process because the interface cannot make a judgment call when it encounters an unexpected situation. The error handling in this situation is also limited to that provided within the function. However, there is a place for these types of interfaces. They have been successfully deployed in very stable and simple environments, when development of a new interface is not an option, and when there is no cooperation among vendors to provide an electronically integrated approach.

4.4 Conclusion

The demands placed on healthcare providers to improve quality, reduce costs while maintaining efficiency, and increase revenues can only be achieved through full implementation of a comprehensive clinical information system. A fully integrated system should provide an up-to-the-minute clinical status report accessible to all appropriate care givers from workstations in a clinical ancillary department, the bedside, or remotely from alternate care facilities, the patient's side, the physician's office or home. This comprehensive up-to-the-minute status facilitates evaluation of treatment and faster response to critical situations, thus improving patient care and reducing the length of stay.

The advances in technology have provided the healthcare industry enormous opportunity for reducing patient care costs by reducing length of stay while increasing efficiency and improving quality of care. While sophisticated departmental clinical information systems continue to improve on information capture, flow, and presentation, the full benefits of a clinical information system cannot be realized until all clinical information is efficiently integrated and effectively presented. Technology has opened the door to allow incorporation of portable hand-held and pen-based devices into the daily work flow for real-time and efficient collection of patient care activities and the electronic transfer of this information via wireless LANs or other appropriate connectivity options to provide on-line, real-time access to care providers and clinicians. As a byproduct of accurate and timely data collection, technology also pro-

vides the ability to store massive amounts of information in an open architecture for retrieval of information to monitor and improve patient outcomes.

We are limited only by our ability to imagine and create the clinical information systems that complete the cycle of bringing efficiency and effectiveness to all clinical departments and provide a complete integration of appropriate clinical information.

4.5 References

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5.0 CLINICAL INFORMATION SYSTEMS IN CRITICAL CARE

by: Thomas East, PhD and Richard M. Sailors, ME

Computers and health information have been linked for over 100 years. The 1890 census tabulation was one of the first large scale uses of the calculating machine.[1] The introduction of the minicomputer and the microcomputer in the 1970s dramatically increased the availability of computers. It was during this era that computers first began to be routinely used in hospitals and intensive care units (ICUs). The proliferation of the early IBM personal computer (PC) and clones in the early 1980s greatly enhanced the spread of computers in healthcare settings in general and the computing power available to the average user. The last several years have seen the computing power of the desktop PC increase dramatically, while the cost has decreased.

Why would anyone use a computer as a part of critical care? An examination of the history of computers shows they were created to help the human mind deal with large amounts of information, complex mathematics, complex data manipulation, and to automatically do well-defined, repetitive tasks. There are few arenas in

healthcare that are as complex, data intensive, and associated with well-defined repetitive tasks (such as management of mechanical ventilation) as a modern ICU. Since the late 1970s, the fundamental operation of the many critical care and life support devices has been increasingly turned over to microprocessor control.[2] Besides their computing aspects, microprocessor systems provide an excellent platform upon which to build devices that can easily be modified and updated. Microprocessor controlled systems make it easy (with software changes) to modify devices without changing expensive physical components. As a result, an explosion of devices and monitoring techniques occurred during the 1980s. The purpose of this chapter is to review the current state of the art as well as future applications of computers in critical care, with particular attention paid to respiratory care applications. Respiratory care applications are of special interest as they involve the interfacing of medical devices to information systems for many different purposes, including automated charting, decision support and closed-loop control.

5.1 Current State of the Art

Despite the large amount of clinical care data and the obvious difficulty in managing it in a handwritten record, critical care information systems have not seen widespread acceptance as a method for recording information during critical care. Much of the explanation lies in the question of cost justification of such systems as these systems are typically cost justified based on reduced time spent on charting and doing record audits. The implication of the reduced charting time is that money would be saved by reducing staffing requirements. Andrews et al. reported that the respiratory care charting portion of the HELP system at LDS Hospital was associated with an 18.2% increase in productivity and a 20.9% increase in work volume.[3] Full-time equivalent (FTE) staffing requirements, however, did not change. An average of 2.6 minutes was spent in documentation in 1984, as compared with 1.37 minutes in 1992.[4] However, Pierpont and Thilgen reported no net increase in time for tasks unrelated to data manipulation after the Minneapolis VA Medical Center's installation of a computerized charting system.[5] The claim that information systems are cost justified based upon reduced FTE requirements is controversial. Hammond et al. demonstrated that a patient data management system (PDMS) can significantly reduce the number of errors found in paper flow charts[6] and improve the quality, accuracy and timely capture and retrieval of data. They did not, however, show a reduction in the required nursing FTEs.[7] Additionally, Bradshaw et al. showed that less nursing time was spent on direct patient care (a reduction from 49.1% to 43.2%) and an increase in time spent on clinical data entry (18.2% to 24.2%).[8] There are many anecdotal reports of the impact of such systems on the quality of patient care; however, there are few conclusive studies that clearly demonstrate improvement in the quality of patient care. One would assume that the improvements in the quality of the patient chart would impact the quality of patient care; however, some have estimated that it would require a study of at least 6000 patients to be able to statistically illustrate any impact on patient outcomes[9] (assuming a reduction in mortality from 16 to 14.4%). It may be possible to observe an impact on the quality of patient care by looking at other intermediate indicators such as the length of stay, incidence of mistakes, etc. It is essential that carefully designed studies be conducted to evaluate the impact of these systems. These studies must include social as well as technical issues and address not only bench

testing but usability testing and strive to avoid the biases due to pressure from the entities funding the evaluations.[10,11]

The current focus on total quality management (TQM) in the healthcare industry has led some to expand the scope of information system evaluation. One approach is to focus on achievement of benefit as the primary evaluation goal, and the maximization of the ratio of achieved benefit to maximum benefit as the primary outcome measure.[10] However, Shabot et al. reported reduced time spent on quality assurance (QA) and utilization review (UR) as a by-product of the use of an ICU information system at Cedars-Sinai Medical Center, in addition to the TQM benefits.[12]

The main problem with demonstrating efficacy of information systems for the ICU may be that the current systems focusing on automation of the charting process do not really address the needs of the clinician in the ICU environment. What are the real needs of the clinician (RN, MD and RT) at the bedside? We recently went to the bedside of one critically ill patient and counted the concurrent information categories (not repeated measures) that were reviewed one morning during ICU rounds. The total number of variable categories was in excess of 236![13] Dr. Eddy summarized it best: "It is simply unrealistic to think that individuals can synthesize in their head scores of pieces of evidence, accurately estimate the outcomes of different options, and accurately judge the desirability of those outcomes for patients. All confirm what would be expected from common sense: The complexity of modern medicine exceeds the inherent limitations of the unaided human mind."[14] The next generation of computers for critical care must help the clinician to assimilate the myriad of data and to make fast and effective decisions. It is not enough to merely display the data in a large spreadsheet or on a complex, colorful time-sequence graph. New data display concepts and expert systems need to be included in commercial products. Very few clinical information systems (CISs) for the ICU currently provide any tools for decision support, and most only support time sequence graphs and flowsheet data display. The next generation of ICU computer systems will have to include computerized patient records (CPRs). The following is a list of features that ICU Clinical Information Systems and their CPRs must include if they are to have a significant impact on the quality of patient care: multiview clinical data repository; clinical lexicon; robust, multisource charting; intuitive and customizable user interface; and tools for decision support. Although not strictly an information system issue, we will briefly discuss the issues of security, confidentiality, and authentication separately, and then discuss the remaining issues as they relate to the critical care arena.

5.2 Security and Confidentiality

A CIS which does not provide for both the confidentiality of and access to patient data is not in a position to survive into the next stage of development. The CIS must assure that all of the information necessary to care for the patient is easily available to authorized users, but that no information is available to those without a "need-to-know."

The issue of security and confidentiality of both paper and computerized patient health information has caused a great deal of discussion during the past five years,[15-34] and has now led to the formation of an ASTM (American Society for Testing and Materials) working group on standards for the security of computer-based patient records.[35] These discussions range from patient identifiers and their public availabil-

ity, to behavioral issues, to methods of securing data during electronic transport, to the legal and ethical requirements of computerized record systems.

In 1995 a bill was introduced in the United States Senate which was designed to clarify the application of the Privacy Act of 1974[36] to medical records.[37] The Medical Records Confidentiality Act of 1995 provides guidelines for authorized disclosure of information for healthcare, public health, and judicial and law-enforcement reasons with certain provisions. Criminal and civil penalties for disclosure violations are also set out.

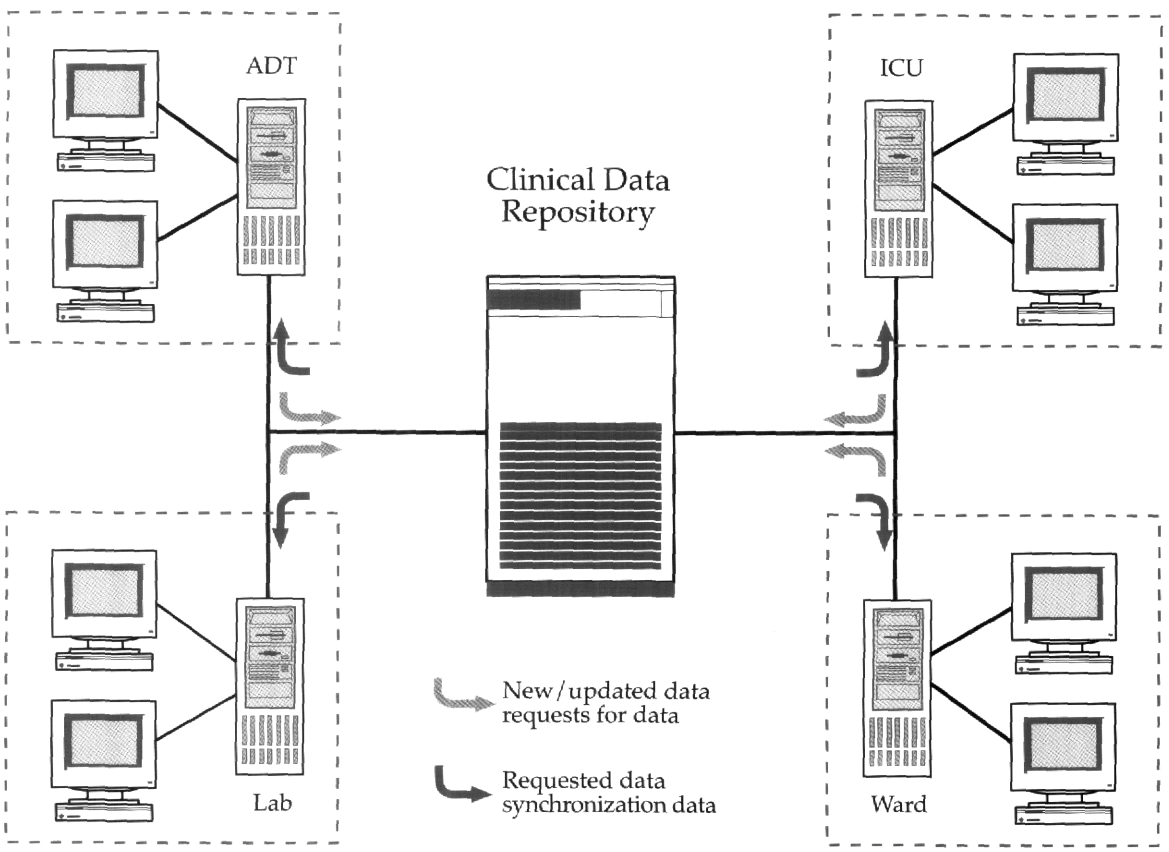
Electronic means of authenticating data are now being standardized. These "electronic signatures" are used in place of printing out a piece of paper and physically signing it. Electronic signatures usually consist of a code or phrase which is unique to the user in question. In this manner it is similar to professional license numbers and ideally social security numbers. The use of electronic signatures conforming to ASTM standards for authenticating health information is encouraged.[38,39] The ASTM specification addresses nonrepudiation, integrity, independent verifiability, multiple and countersignatures, and the transportability and interoperability of electronic signatures. The Institute of Medicine has recognized electronic validation as one of the keys to computer-based patient records.[39] Possible methods of assigning electronic signatures are random number generators, professional license numbers, state codes and user-chosen words, and algorithms to convert a measurable physical characteristic into a number (such as retinal scans, fingerprints, voice, or eventually genetic codes). A common method of assigning, storing, and validating electronic signatures must be implemented before they can become as commonplace as traditional signatures.

5.3 *Clinical Information System Features with Examples from Respiratory Care*

5.3.1 Multiview Clinical Data Repository (Integrated Database)

A system should include data from more than just the ICU. A clinical data repository (Figure 5.1) contains integrated information from a myriad of sources: admit, discharge and transfer (ADT), labs, radiology, operating room (O.R.) and outpatient clinics. The introduction of prospective reimbursement has caused a shift to performing as many tests as possible on an outpatient basis before hospitalization. It is essential that data from these outpatient visits be available and be integrated with the ICU data.[40, 41]

Figure 5.1 – A clinical data repository (CDR) is an integration center for data from all areas of medical care. All medical data which is collected is sent to the repository for storage and integration. Any information requested by clinicians in any of the various healthcare settings is sent from the repository to the local machines. Any data changed in either the repository or on a source system (such as the laboratory) is synchronized with the other machines. So, if a lab result is edited on the laboratory machine, the change is sent to the CDR which then passes the change on to the other systems.



The clinical data repository of a successful system must include data synchronization between the main database and all source databases, and must guarantee accurate and timely data (< 1 minute response time delays).[42] Data retrieval should be rapid, as most clinicians are unwilling to wait more than three or four seconds for a response from the system.

The ability to present data in multiple views adds additional value to clinical information systems. The primary views needed for critical care are by patient, by provider, and by diagnosis. By transcending the paper-based paradigm of "one patient-one record," the clinical data repository allows the information system to provide management information, outcomes measures, and track population health. For example, possible sources of nosocomial infections can be easily identified by viewing microbiology results sorted by healthcare provider, and the effects of a process care model can be assessed by viewing all patients with a given diagnosis. With current systems the easiest way to obtain this kind of information is often to perform data analysis outside of the clinical information system.[43] Other views include encounter- and episode-based information. While these views are not as important in the critical care arena, they are necessary parts of an integrated clinical data repository, especially with the current movement toward establishing local, regional, national and international databases that would track all information on a patient from birth to death.[40]

5.3.2 Controlled Vocabulary and Clinical Lexicon

A controlled vocabulary and clinical lexicon work symbiotically with the integrated database to form the core of the computerized patient record. A controlled vocabulary eases the burden of coding the information in the database by limiting the terms which can be used. The clinical lexicon is a dictionary of concepts within the CPR. Each concept is uniquely identified by a code which can then be mapped into various synonymous terms for different users. For example, the concept "arterial hemoglobin saturation, measured by pulse oximetry" could be identified by the concept code "11384", but clinical lexicon would also know that the terms "SpO_2", "pulse ox. sat.", "oximeter sat", and "HbO_2 %" all describe the same concept. Since the database will only refer to concepts (e.g., "arterial hemoglobin saturation, measured by pulse oximetry") by their concept identifiers (e.g., "11384"), all database transactions must either use this identifier or be brokered by an interpreter which maps text requests to the proper concept identifier. The clinical lexicon helps insure against redundancy in the database and insures that all database users are using a common terminology set. By limiting the terms available to the user, a controlled vocabulary also makes the clinical lexicon easier to maintain and further helps reduce redundancy. The codes used in the clinical lexicon can either be public codes, such as ICD (International Classification of Diseases), or proprietary, such as in the example above or the PTXT (Pointer-to-TeXT) in the HELP (Health Evaluation through Logical Processing) system.[44] Table 5.1 lists some of the more commonly used coding schemes and their common applications.

Table 5.1 – Common coding schemes for medical information.

Common Coding Schemes for Medical Information		
ICD	International Classification of Diseases	Classification of inpatient diagnoses. Used internationally to classify morbidity/mortality and reported to World Health Organization. Used in U.S. for billing/reimbursement.
DRG	Diagnosis Related Groups	Classification of inpatient diagnoses. Lumps similar (by cost) diagnoses into larger groups than ICD. Used for billing/reimbursement in U.S.
CPT	Common Procedural Terminology	Classification of outpatient procedures for reimbursement/billing in U.S.
Reed		British National Health Service coding system which covers all clinical terms and concepts.
SNOMED	Systemized Nomenclature of Medicine	System from American College of Pathologists for coding clinical concepts
UML	Unified Medical Language	National Library of Medicine (U.S.) system for coding all clinical terms and concepts

The clinical lexicon is also well suited to multilanguage sites and to tailoring the text output from the database to the class of user to whom it is displayed. Thus clinicians who speak Spanish, German, French, and Dutch all use the same concept identifier even though the text they see is in their own language, and while a clinician sees the concept "09023" as "otitis media", the patient reading computer generated management plan will see "ear infection." A universal clinical lexicon and controlled vocabulary will become a 21st century version of Esperanto®, a synthetic language designed to provide a common basis for communication.

5.3.3 Robust, Multisource Charting

The successful CIS must allow robust multisource charting. The charting tools must include tools which facilitate manual data entry, support automated charting and provide integrity checks for both manual and automated charting.

5.3.3.1 Manual Charting

Manual data charting must provide a benefit to the users of the CIS. Data should be collected only once and as close to the source of generation as possible. The data entry mechanism must be easy to use; this implies that it is logical, rapid, and consistent. Computerized data entry should require no more effort than current hand charting while providing integrity checks to improve the quality of the data. There are several paradigms currently being used to design manual charting systems. The

two most commonly used paradigms are computerized ICU flowsheets and point-of-time charting. While the ICU flowsheet is a compact, multidisciplinary chart, it is not necessarily the best paradigm for computerization. For comparisons of various user interface paradigms for data entry, see "Intuitive and Customizable User Interface."

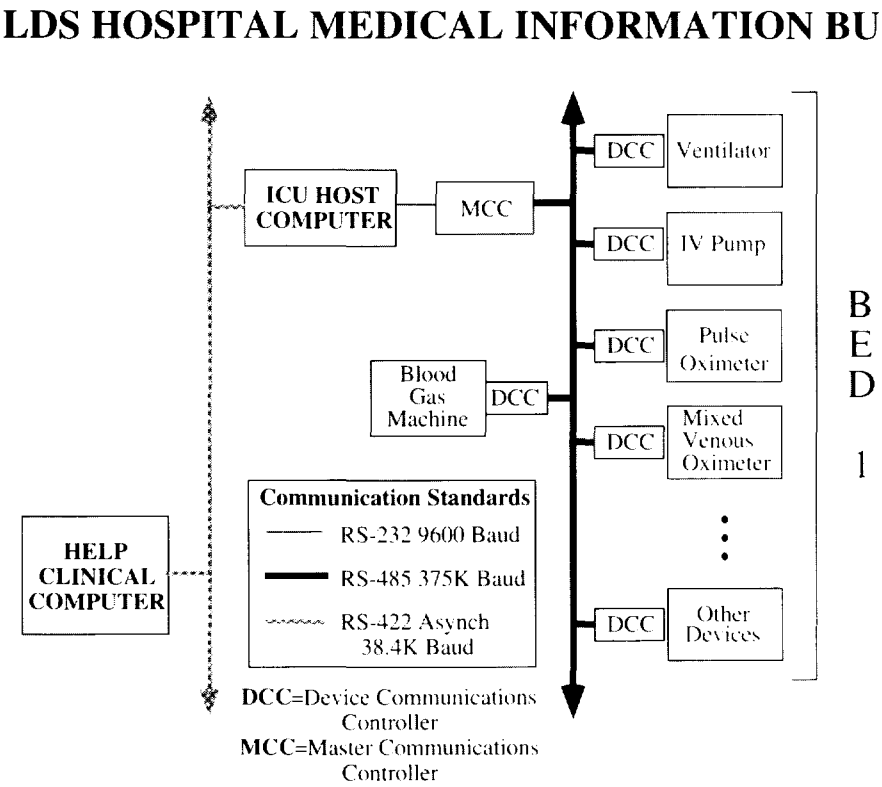
5.3.3.2 Automated Charting

To facilitate automatic data acquisition from a wide variety of medical devices, a Medical Information Bus (MIB) is being developed and is being standardized by the Institute of Electrical and Electronics Engineers (IEEE, New York) so that all hospitals and vendors can use a common data format and easily communicate with multiple bedside devices.[46, 55-59] The MIB provides a local area network (LAN) around the patient which can be interfaced to all bedside devices and allows data from each of the devices to be stored in a central database in a standard format.[60-63] The MIB handles issues unique to the medical data communications environment such as the need for automatic recognition of new devices placed at a bedside, automatic reconfiguration of the network, and association of a device to a particular patient's bedside.[46, 59] Unfortunately, the current MIB standard does not include standards for artifact rejection and significant event identification.[45, 54] It is ironic that the largest amount of effort in developing the MIB standard has been spent on standardizing digital communication and these are the least important to medical decision making.

There are several successful research information systems in which a variety of medical devices have been interfaced to computers using the existing proprietary interfaces. Shabot et al. at Cedars-Sinai in Los Angeles, CA, have interfaced their Hewlett-Packard ICU computer system to the Puritan Bennett 7200 ventilator, pulse oximeters, urimeters and other critical care devices.[45-47] Individual research systems that interfaced ventilators,[48-53] IV pumps, pulse oximeters, mixed venous oximeters, and urimeters[13, 53, 54] have been developed at LDS Hospital, Salt Lake City, UT, and the University of Utah.

A preliminary version of the MIB was installed at the 520 bed LDS Hospital and connected to the HELP system[45, 54, 64, 65] (Figure 5.2). An MIB interface for ventilators has been constructed at the LDS Hospital,[47, 53] and we have completed studies investigating techniques for identifying artifacts and significant events.[66] Data were collected for 617 hours from 10 patients ventilated using the Puritan Bennett 7200 ventilator. Data from the ventilator were sampled at 10-second intervals and stored in a research database, which was then used to examine 6 different filters designed to eliminate artifact: moving average, moving median, two different moving exponentially weighted averages, LOWESS (a robust locally weighted regression technique)[67] and a moving LOWESS. Significant events were identified as values being above a defined threshold for a period of time (both 1 and 3 minute thresholds were tested). The output from each of these algorithms was compared to the concurrent data in the HELP system, entered by the respiratory therapist using the bedside keyboard.

Figure 5.2 – The medical information bus (MIB) on HELP System.



There were some differences between ventilator settings charted by the RT and the MIB. The "error" rate for manual charting of ventilator settings was 3%. By carefully screening, most of the differences were found to come from RT's "back charting" with the wrong time stamp and the "time delay" of the automated charting algorithms. RTs tended to enter data and stamp it with the time they "thought" was the time the events occurred. Occasionally this time stamp was in error. The error rate for manual charting was reduced to 1% if all the errors caused by back charting were ignored.[66]

Figure 5.3 – Comparison of automatic collection and manual charting of tidal volume data. Note the number of significant events (as defined in Table 5.2) which manual charting misses.

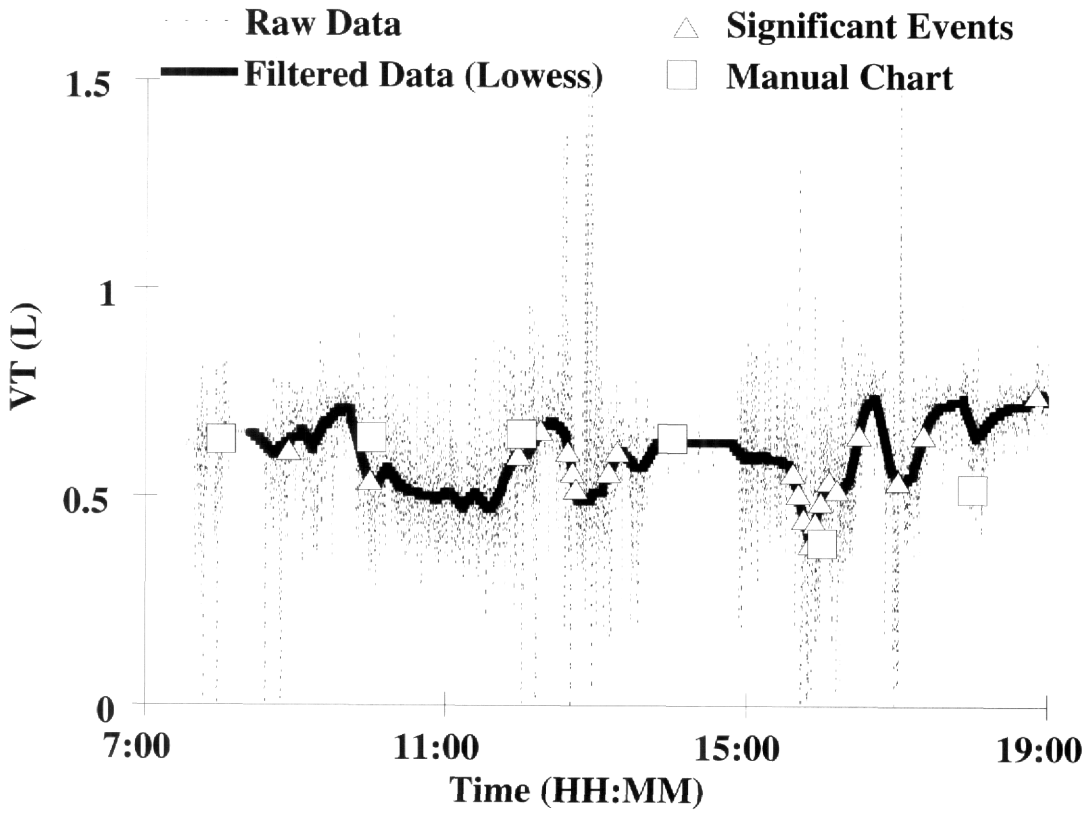


Figure 5.3 is an example of the VT data collected during this study.[53] The raw data contained a lot of "noise" and "artifact." In general, all the filtering algorithms helped to reduce artifact; however, the moving LOWESS filter performed best. The disadvantage of the moving LOWESS filter is that it requires much more computer time than a simple moving median. The moving median seemed to be the best choice because it did not follow transients and was relatively simple to implement. There were large differences in the number of events found by the filtering algorithms to be "significant" from those charted manually. Two main differences were observed: 1) the therapists do not chart what occurs when they were not at the bedside; and

2) when they chart, they typically just take a "snap-shot" for a few seconds as they are working on the ventilator that may not really be representative of the patient. Our recommendation for an optimum algorithm for automated respiratory care charting is shown in Table 5.2.

Table 5.2 – Recommended algorithm for automated respiratory care charting.

1. Sample all data from ventilator every 10 seconds and hold in buffer

2. Report any ventilator setting of more than 3 minutes' duration
   - Ventilation Mode (MODE)
   - Ventilator Rate (V_R) or IMV Rate
   - Tidal Volume or Minute Ventilation (VT or VE)
   - Peak Inspiratory Flow
   - Inspired Oxygen Fraction FiO_2
   - Trigger Sensitivity
   - Positive End Expiratory Pressure (PEEP)
   - Pressure Support or Control Level
   - Flow By Support Level
   - Flow By Sensitivity

3. Measured Data:
   a. Use 3 minute moving median to filter raw data stored in buffer
   b. Report one filtered value every hour
   c. Report significant events:

Peak Pressure	Change > 10 cm H_2O	*and*
	3 cm H_2O < Peak Pressure < 120 cm H_2O	
Airway Pressure	Change > 5 cm H_2O	*and*
	3 cm H_2O < Airway Pressure < 120 cm H_2O	
Plateau Pressure	Change > 5 cm H_2O	*and*
	3 cm H_2O < Plateau Pressure < 120 cm H_2O	
I/E Ratio	Percent Change > 25%	
Spontaneous V_T	Percent Change > 10%	*and*
	Change > 100 mL	*and*
	100 mL < Spontaneous V_T < 2500 mL	
Machine V_T	Percent Change > 10%	*and*
	Change > 50 mL	*and*
	100 mL < Machine V_T < 2500 mL	
Spontaneous V_R	Percent Change > 10%	*and*
	Change > 5 bpm	*and*
	0.5 bpm < Spontaneous V_R < 70 bpm	
Machine V_R	Percent Change > 10%	*and*
	Change > 2 bpm	*and*
	0.5 bpm < Machine V_R < 70 bpm	

   that last for over 3 minutes
   d. Report all measured data values 1 minute after setting changes

There is little or no data on how automated charting of mechanical ventilation data may impact patient outcome. In a recent study, the authors of this chapter found that ventilator setting charting errors could be reduced from about 3% to near 0% by instituting automated charting. For measured parameters, automated charting found significant events that previously went undetected. However, there are no studies about what impact these results might have on patient care. Automation of other areas of the patient record has been shown to improve the quality of the data and reduce the amount of time spent on charting. If electronic communication with mechanical ventilation is to become an effective and routine part of clinical care, then we must move forward to standardize digital communication with these devices. A standard, such as the MIB, must be adopted that makes it easy to physically connect the devices. In addition, we need more research into the elusive definitions of "artifact" and "significant events." In the next ten years, bedside clinicians must take an active part in this standardization process. Without clinical input the standardization process is doomed to failure from the beginning. We anticipate that one day connecting a ventilator to the computer will be as simple as plugging in your telephone, and that the quality of the data could be relied upon to be valid and representative of the patient's true condition.

- Integrity Checks: A decision is only as good as the data on which it is based. If data is incorrect, missing, inconsistent, or not correlated with the other pieces of data, the decision based on it is of questionable validity. Data integrity is important at all stages of decision making, but is especially important when the decisions being made are about healthcare. Decision support systems are only as good as the data they present. Whether the support is based on expert systems or only data presentation, incorrect data can lead to dangerous, even fatal consequences. Regardless of the method of data collection (automated or manual), data integrity is key to insuring the quality of the data in the database and the decisions based on that data. Data integrity should be enforced as close to the point of entry as possible. The farther from the point of entry data integrity checks are performed, the more difficult and time consuming the task. The concept of data integrity encompasses several key areas: data completeness, ranges, and referential integrity.[68]
- Data Integrity: All available data should be entered at the time the data is generated. This means at the ICU bedside, in radiology, the O.R., or anyplace else patient care is performed. If values are missing, patient care can be affected. Charting by exception and default values are two methods of easing the charting burden and helping to assure data completeness.

- Range Checking: Range checking is vital to insure correct charting of values in the computer. It is all too easy to miss the decimal point and change a pH from 7.24 to 72.4 or transpose an oxygen saturation of 87% into 78%. While the pH is clearly wrong, both the correct and mistyped saturations are logically possible, but the decision based on one may be vastly different from the decision based on the other. Without range checking, this bad data can propagate throughout the system and lead to adverse outcomes. Automated decision support aids are especially vulnerable to erroneous data. Table 5.3 illustrates some of the range checking performed by ventilator charting screens recently designed for LDS Hospital and Intermountain Healthcare, Inc. (IHC). As Table 5.3 shows, both absolute and warning ranges are needed for completeness. The warning ranges may be tailored to sites and intensity of care. A clinician might not be concerned by an ICU patient presenting with a SpO_2 of 88%, while he is deeply concerned if a ward patient's SpO_2 is that low, but neither patient should have a charting of 105% saturation.

Table 5.3 – Sample range checking criteria for Servo 900c ventilator. Copyright 1995, Intermountain Healthcare, Inc.

Sample Range Checking Criteria for Servo 900c Ventilator				
Variable	**Reasonable Low**	**Reasonable High**	**Absolute Low**	**Absolute High**
% O_2	21	100	21	100
SpO_2	70	100	30	100
VE	2.0	25.0	0.5	40.0
VR	5	80	5	120
PEEP	0	30	0	50

%O2=inspired oxygen fraction (percent); SpO2=pulse ox. saturation; VE=minute ventilation; VR=ventilator rate setting; PEEP=positive end expiratory pressure

A warning message is generated if the value of the variable falls outside of the Normal Low to Normal High range. Entering values outside of the Absolute Low to Absolute High range is not allowed.

- Referential Integrity: Referential integrity checking verifies that related values are consistent and rational. For example, the hospital discharge date must not be before the hospital admit date. Table 5.4 lists some common referential integrity rules.

Table 5.4 – Sample referential integrity checks.

Variable	Rule
Peak Pressure	>= Plateau Pressure
Plateau Pressure	>= PEEP and <= Peak Pressure
PEEP	<= Plateau Pressure
Measured Rate	>= Set Rate
Systolic Blood Pressure	>= Diastolic Blood Pressure
Diastolic Blood Pressure	<= Systolic Blood Pressure
ICU Admit Date / Time	>= Hospital Admit Date / Time
Hospital Admit Date / Time	<= ICU Admit Date / Time
Date of Birth	<= Hospital Admit Date / Time

PEEP=Positive End Expiratory Pressure

While some rules are inter-related and may seem redundant, they are all required to handle situations where data is not charted in order expected or is edited at a later date.

This information appeared in slightly different form in (Carlson, 1995) and the accompanying presentation. [68]

In the current randomized trial of computerized protocols for ARDS ventilator therapy, the authors have instituted these types of integrity checks in our data collection process, both at the point of entry and prior to data analysis.[68] Their data error rate (measured as number of datum which are wildly improbable or erroneous and not found by automated checks or form-based QA criteria divided by total number of new datum) is currently less than one percent (< 1%) as compared to an estimated rate of 3% (measured as number of datum which are wildly improbable or erroneous committed to our database divided by total number of new datum) in the raw data and 3% in historical controls.

5.3.4 Intuitive and Customizable User Interface

Effective and efficient data entry, review, and use require an intuitive user interface. The user interface encompasses both the computerized interfaces for data entry and review and computer-generated reports. The user must be comfortable with the interface and be able to effectively review and enter data. To this end, the user interface must be intuitive and customizable. The intuitive user interface should use common procedures and consistent visual composition. The user interface should not hinder the user with unnecessary "gimmicks" and must not decrease either the efficiency of data entry or the quality of the data.

The user interface should also be customizable to either the individual user or by the user's job category. This customization should not be initially available to the user but only be available by formal request to the information services personnel and only after the user is experienced enough to know what does and does not work for him. The initial customization should provide the user only the appropriate information for decision making, data charting, and review. For example, a ward clerk

does not need to be able to chart medication delivery, but should be able to review all given medications, while a nurse should be able to both chart and review medications. Data summaries and overviews are important tools for data review, but at all times all data must be available on request through "drill down" functions and queries. Insulation from information overload will become a greater benefit as the technology for data generation and sharing improves. A day in the not too distant future will see clinicians trying to make sense of gigabytes of patient information. One of the primary functions of the information system will become protecting the clinician from too much information.

Most CISs now allow the user to view and enter data in multiple forms. The most popular forms are flowsheets, point-of-time entry, and time sequence graphs. The popularity of the flowsheet is due to its similarity to the paper flowsheets commonly seen in ICUs. Data is presented in a time sequenced fashion (Figure 5.4), with review and correction of previous data only a few keystrokes away. Point-in-time screens show a snapshot of the data from only a single point in time (Figure 5.5). The time sequence graph is used only for data display and review, but not for charting (Figure 5.6).

Figure 5.4 – Characersitic flowsheet paradigm charting screen. Copyright 1995, Intermountain Healthcare Inc.

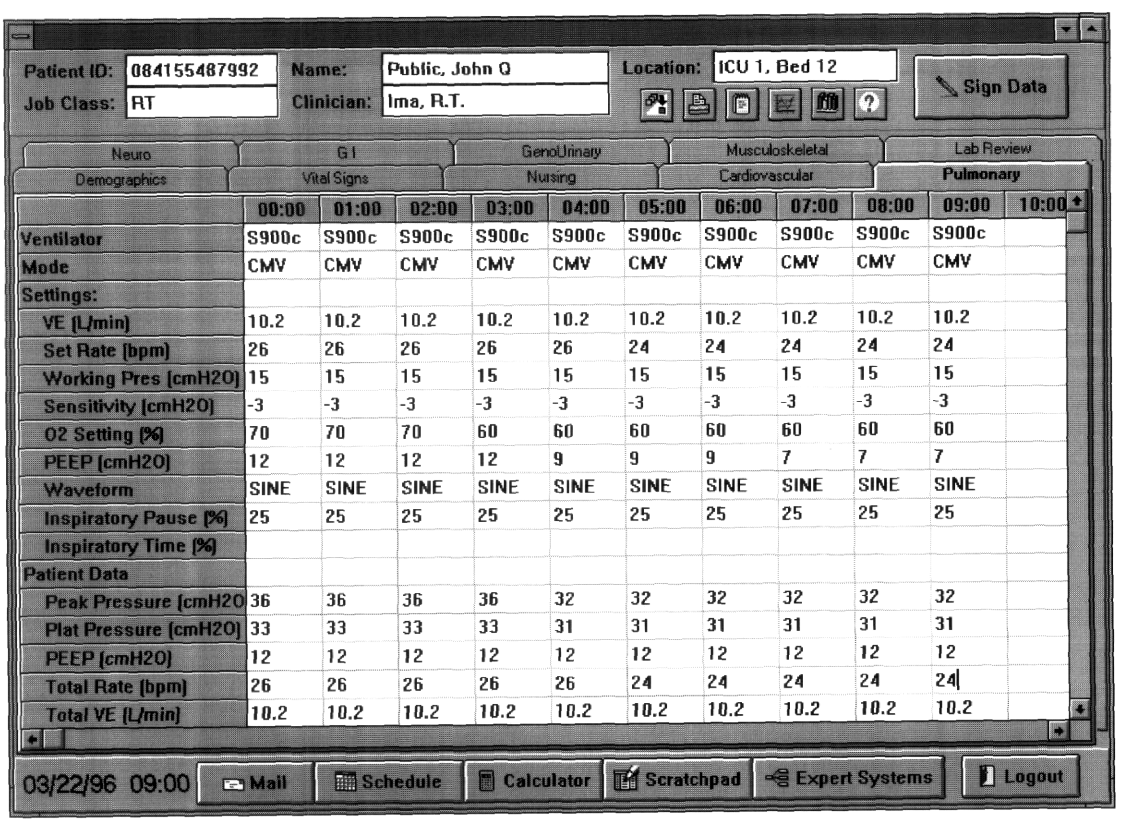


Figure 5.5 – Point-of-time paradigm charting screen. Prototype of adult ventilator charting screen in use at Intermountain Healthcare, Inc. hospitals. Copyright 1996, Intermountain Healthcare Inc.

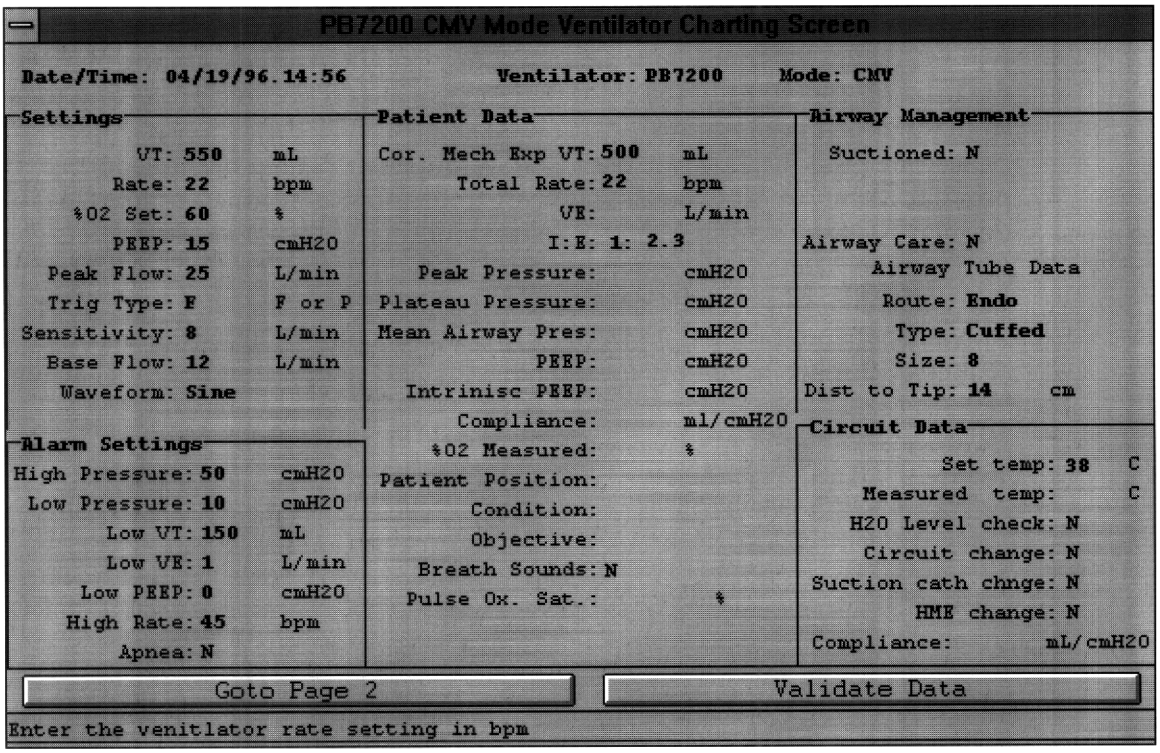
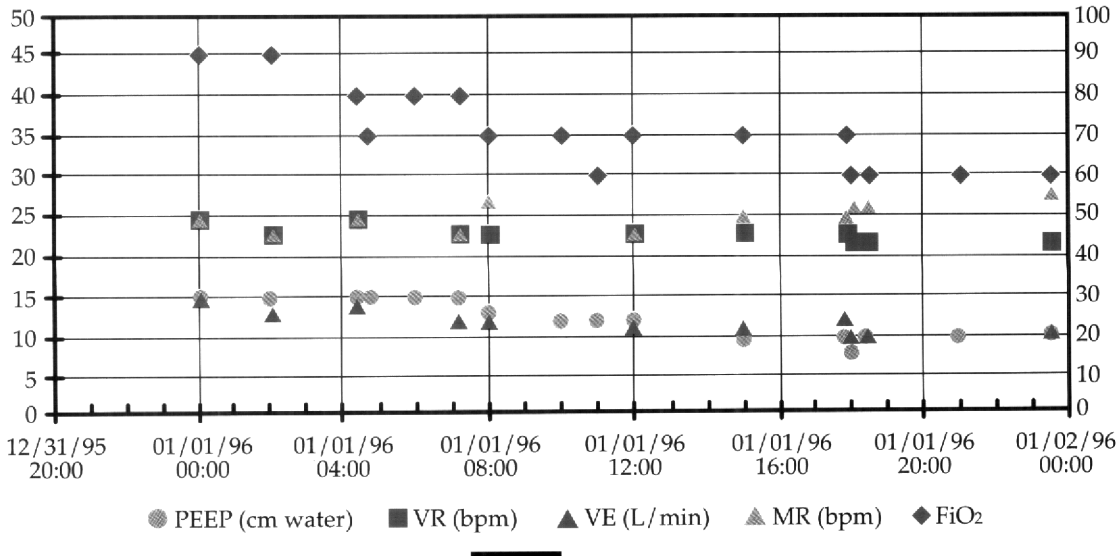


Figure 5.6 – Characteristic time sequence graph showing respiratory care data over a 24-hour period.



The majority of the commercial systems and several of the custom systems have tried to merely reproduce the ICU flowsheet on the computer (Figure 5.4). Although this may ease the transition from pen and paper to computer, there is little evidence that this is the optimal strategy. While the ICU flowsheet is a "one-stop" chart, it is not always easy to navigate and can often contribute to the data overload faced by ICU clinicians. Merely computerizing an imperfect paper charting and review system does not necessarily improve either the usability or quality of the data. There is a disturbing trend among the systems which offer flowsheet-based charting to allow for free form input in many fields with no QA rules. The reasons cited for this are to improve user acceptance and maximize customizability.[69] This free form input unfortunately results in unvalidated (no range or inter-field checking) data which can be confusing to humans and useless to computerized decision support aids. For example, one nurse may mark an "X" in the box indicating the patient was turned, while the next nurse may write "no" and a note explaining why the patient was not turned, and a third nurse may write a "0" to indicate the patient was not turned.[70] Another common example is the charting of FiO_2. Fractional inspired oxygen should be expressed as a decimal; however, many people use the terms "FiO_2" and "percent oxygen" (charted as a whole number) interchangeably and chart FiO_2 as 40 rather than as 0.40. Without a standard method of charting, the data is useless to a decision support tool. This can be rectified by using typed fields (i.e. time, Boolean [yes/no], integer, decimal numbers, alphabetic characters) with range and referential checking and pick lists. Typed fields and pick lists are also important tools for enforcing data quality.

Point-in-time displays are more appropriate for charting than for data review. A point-in-time display, as its name suggests, only displays the data as it appears at a single instant in time (Figure 5.5). While this allows for less cluttered charting, no trend information is displayed, which can make managing a patient difficult. The benefits of typed fields and pick lists also apply to point-in-time displays.

Time sequence graphs are a staple of the healthcare profession. The majority of the graphs used by clinicians are used primarily to call attention to trends in the patient's condition (falling PaO_2, rising serum glucose, falling blood pressure). These graphs are not used as the primary charting or data review tool, but are used to focus the clinician's attention on conditions which need to be more closely investigated. Figure 5.6 shows a typical time sequence graph for an ICU patient. In an advanced computerized system, the user could highlight the data points or time interval he wished to review and the computer would display the data requested in the appropriate form, usually a flowsheet.

The time sequence graph is often ill suited to display the vast amounts of data generated by an ICU stay. By the time all of the lab results, fluid balances, respiratory therapy chartings, and vital sign data are combined, more than 50 common pieces of data must be displayed. A different display paradigm is needed. Some researchers and clinicians are in favor of concept or metaphor graphics[71-79] to represent commonly measured values such as temperature, tidal volume and respiratory rate (Figure 5.7), while others suggest the use of polar graphs to quickly spot abnormalities in lab results (Figure 5.8).[76, 80] Total data abstraction is proposed by still others. These total abstraction systems would display a stylized patient and assign various organ systems to different regions of the displayed form. Different colors or patterns would indicate the status of the various organ systems. More detailed displays and charting screens are obtained by clicking on the appropriate regions (Figure 5.9).[81]

Figure 5.7a – Metaphor graphic data display using volume rectangles to represent respiratory care data. Part a shows the data in tabular form.

Day 1	18	19	20	21	22	23	24	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17
Oxygen	70		70		70		70		70		70		70		70		70		70		70		70	
Tidal Vol	0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9	
Resp Rate	10.0		10.0		10.0		10.0		10.0		10.0		10.0		10.0		9.0		9.0		9.0		9.0	
Spont TV	0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0	
Spont RR	0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0	
Day 2	18	19	20	21	22	23	24	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17
Oxygen	70		70		70		70		60		60		60		60		60		60		60		60	
Tidal Vol	0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9	
Resp Rate	9.0		9.0		9.0		9.0		9.0		9.0		9.0		9.0		9.0		9.0		9.0		9.0	
Spont TV	0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0	
Spont RR	0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0	
Day 3	18	19	20	21	22	23	24	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17
Oxygen	60		60		60		60		60		60		60		60		60		50		50		50	
Tidal Vol	0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9	
Resp Rate	9.0		8.0		8.0		8.0		8.0		8.0		8.0		8.0		8.0		8.0		8.0		8.0	
Spont TV	0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0	
Spont RR	0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0	
Day 4	18	19	20	21	22	23	24	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17
Oxygen	50		50		50		50		50		50		50		50		50		50		50		50	
Tidal Vol	0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9	
Resp Rate	8.0		8.0		8.0		8.0		8.0		7.0		7.0		7.0		7.0		7.0		7.0		7.0	
Spont TV	0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.4		0.4	
Spont RR	0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		1.0		1.0	
Day 5	18	19	20	21	22	23	24	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17
Oxygen	50		50		50		50		50		50		50		50		50		50		50		50	
Tidal Vol	0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9	
Resp Rate	7.0		7.0		7.0		7.0		7.0		7.0		7.0		7.0		7.0		7.0		6.0		6.0	
Spont TV	0.4		0.4		0.4		0.4		0.4		0.4		0.4		0.4		0.4		0.4		0.4		0.4	
Spont RR	1.0		1.0		1.0		1.0		1.0		1.0		2.0		2.0		2.0		2.0		2.0		2.0	
Day 6	18	19	20	21	22	23	24	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17
Oxygen	40		40		40		40		40		40		40		30		30		30		30		30	
Tidal Vol	0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9	
Resp Rate	6.0		6.0		6.0		6.0		6.0		6.0		6.0		6.0		6.0		6.0		6.0		6.0	
Spont TV	0.4		0.4		0.4		0.4		0.4		0.4		0.4		0.4		0.4		0.4		0.4		0.4	
Spont RR	2.0		2.0		3.0		3.0		3.0		3.0		3.0		3.0		3.0		3.0		3.0		4.0	
Day 7	18	19	20	21	22	23	24	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17
Oxygen	30		30		30		30		30		30		30		30		30		30		30		30	
Tidal Vol	0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9		0.9	
Resp Rate	6.0		6.0		6.0		5.0		5.0		5.0		5.0		5.0		5.0		5.0		5.0		5.0	
Spont TV	0.4		0.4		0.4		0.4		0.4		0.4		0.4		0.4		0.4		0.4		0.4		0.4	
Spont RR	4.0		4.0		4.0		4.0		4.0		4.0		4.0		5.0		5.0		5.0		5.0		5 .0	

Figure 5.7b – Metaphor graphic data display using volume rectangles to represent respiratory care data. Part b shows the data in the volume rectangle form. Each charting can show up to two adjacent rectangles, one for the ventilator (left) and one for the patient (right). Deeper rectangles show increased tidal volume. Wider rectangles show increased rate. Darker rectangles indicate higher oxygen concentrations in inspired gas mixture.

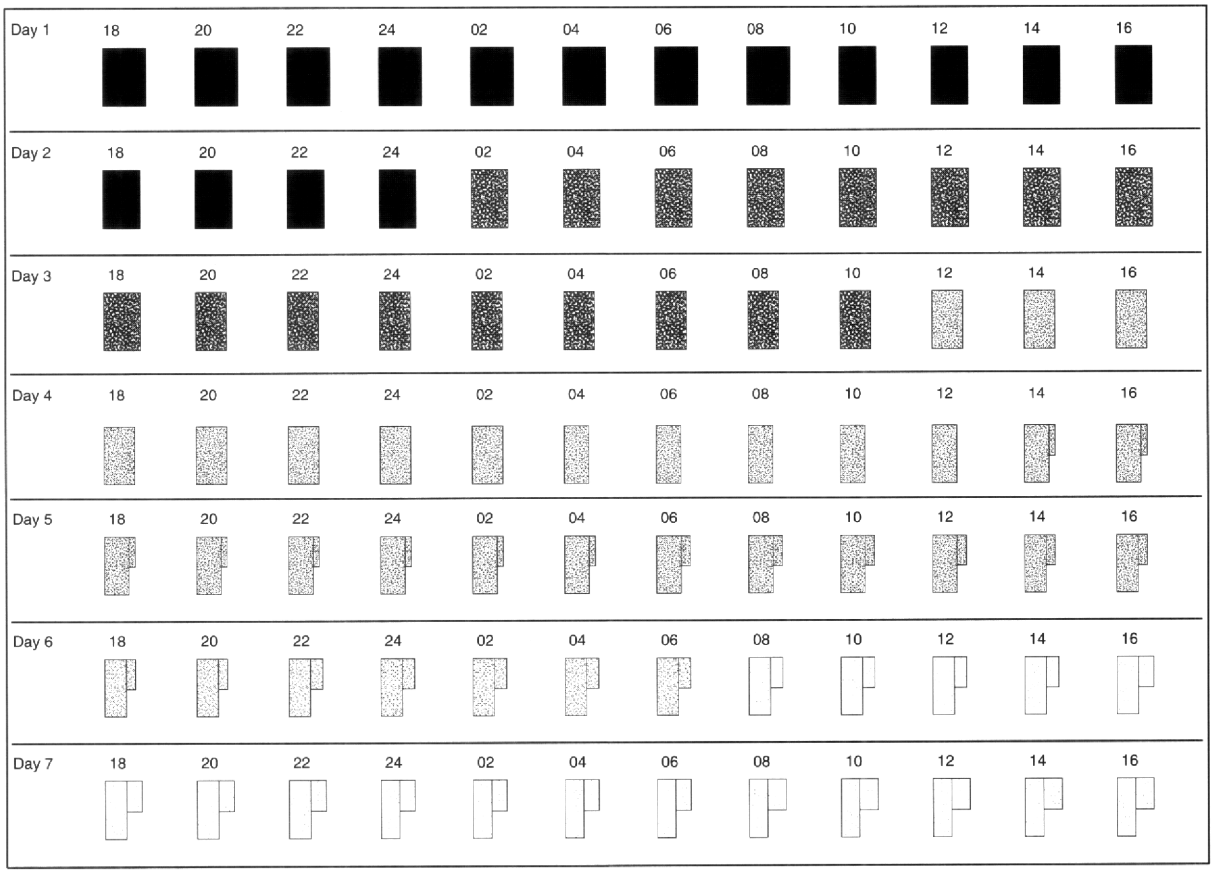


Figure 5.8a – Polar graphs of arterial blood gas (ABG). Normal ranges on each axis are represented by the solid, colored rings.

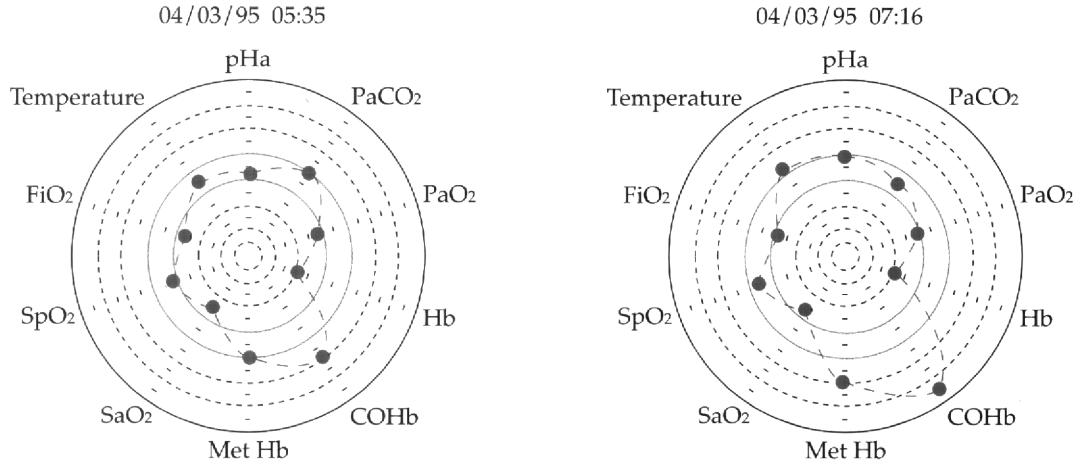


Figure 5.8b –

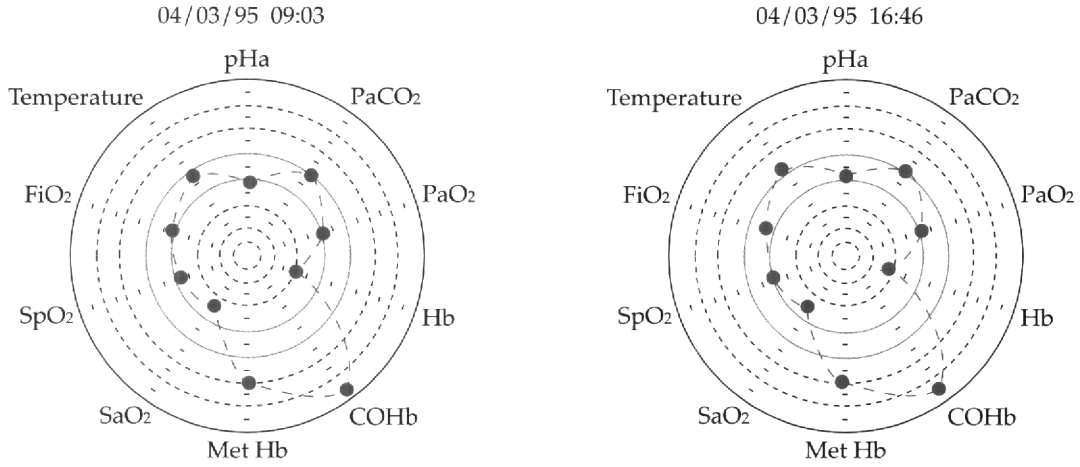


Figure 5.9a – GIFIC (Graphic Interface for Information Cognition) display of ICU patients. The patient on the left has had a heart attack, while the patient on the right is in less critical condition. The various organ systems are represented by unique stylized shapes called Charlottes. The KEGS (Knowledge Enhanced Graphic Symbols) indicate the status of the various organ systems. Copyright 1995, LMI Inc.

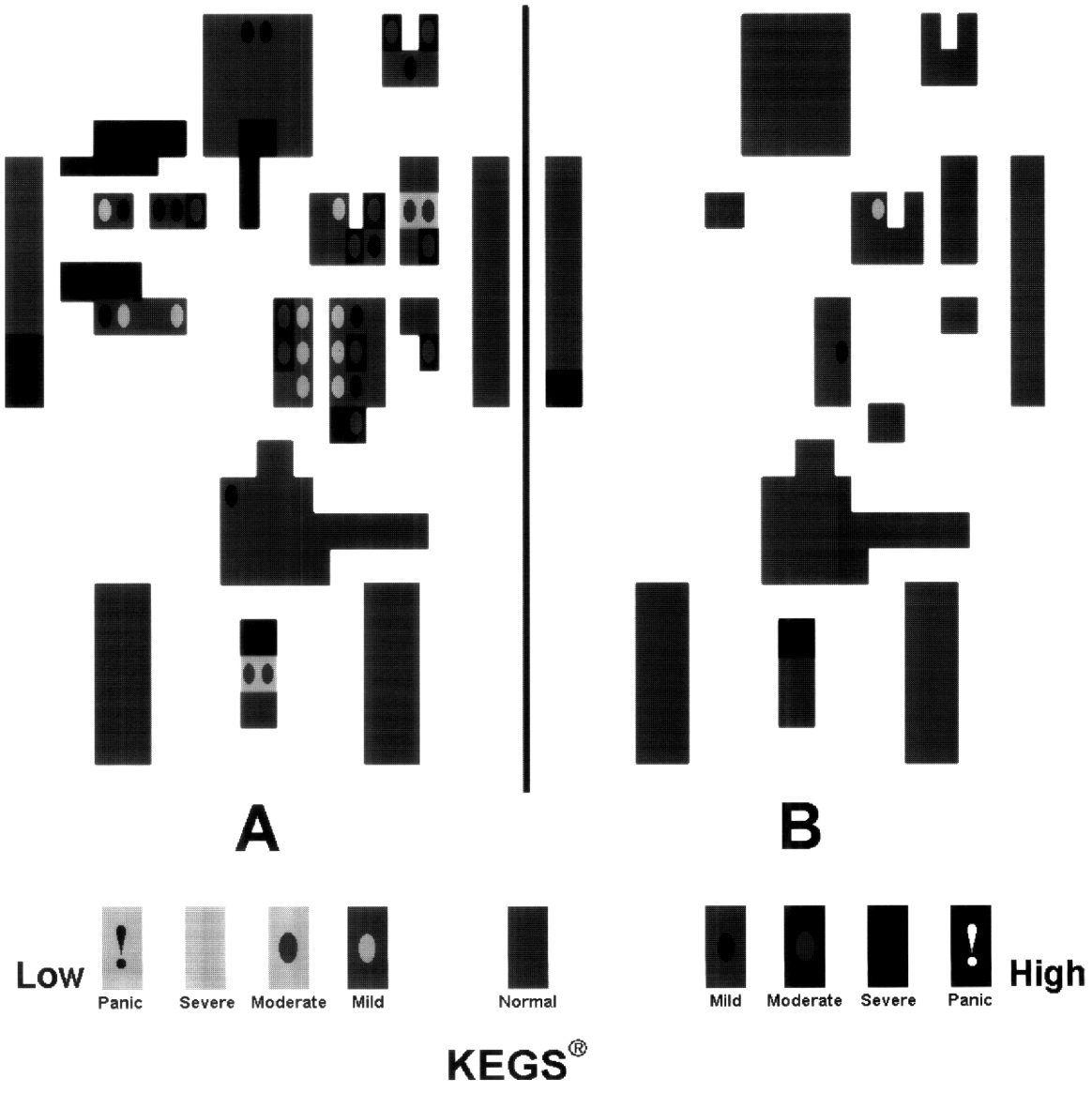
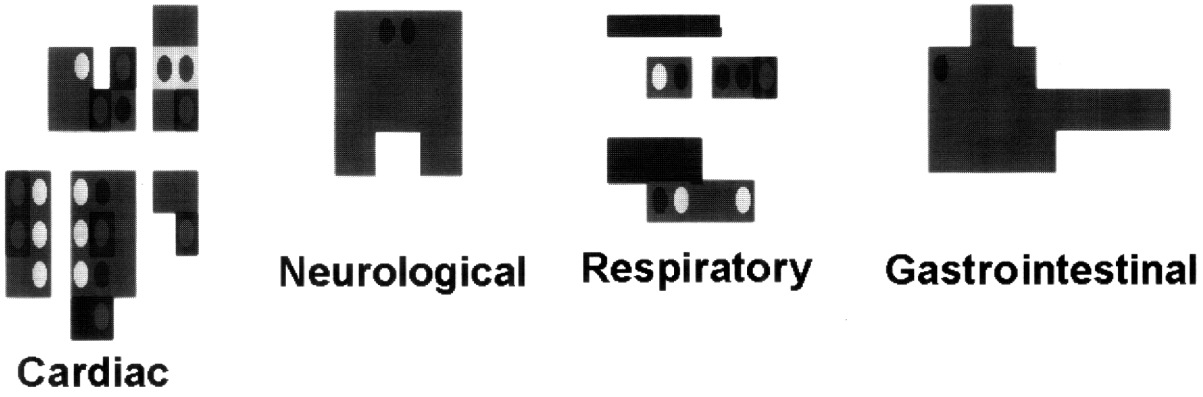


Figure 5.9b – GIFIC (Graphic Interface for Information Cognition) display of ICU patients. Part b shows the Charlottes for four of the organ systems.



This can be extrapolated to the "virtual patient" where less stylized displays are used to show the patient's condition. The patient could be examined by selecting the appropriate part of the anatomy and requesting a detailed view of the system. Figure 5.10 shows an example of this type of interface.

Figure 5.10a – Virtual patient data charting and review screens. An overview of the patient's status customized for a respiratory therapist. Copyright 1995, Intermountain Healthcare Inc.

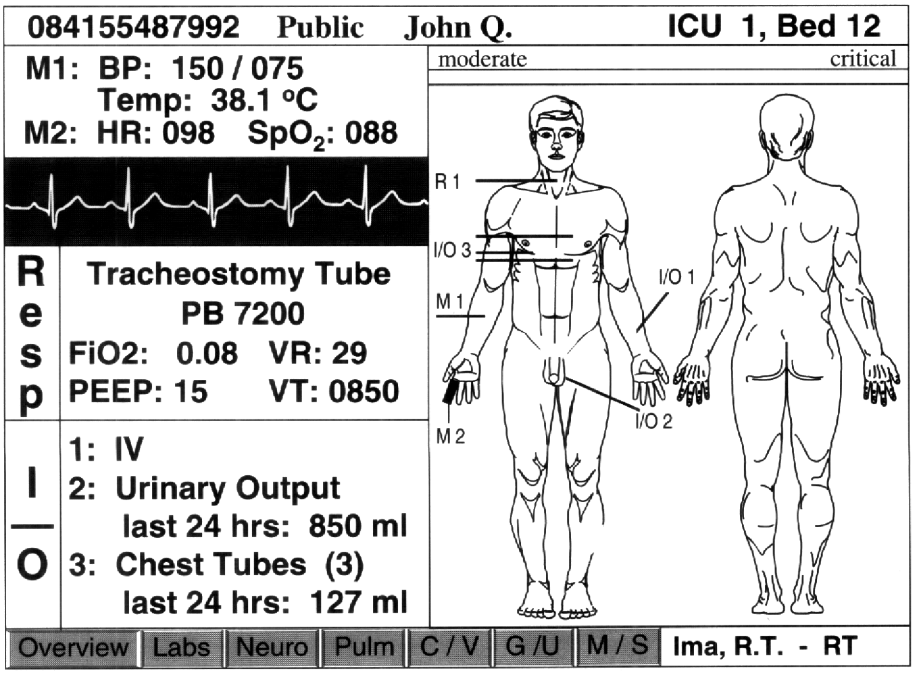
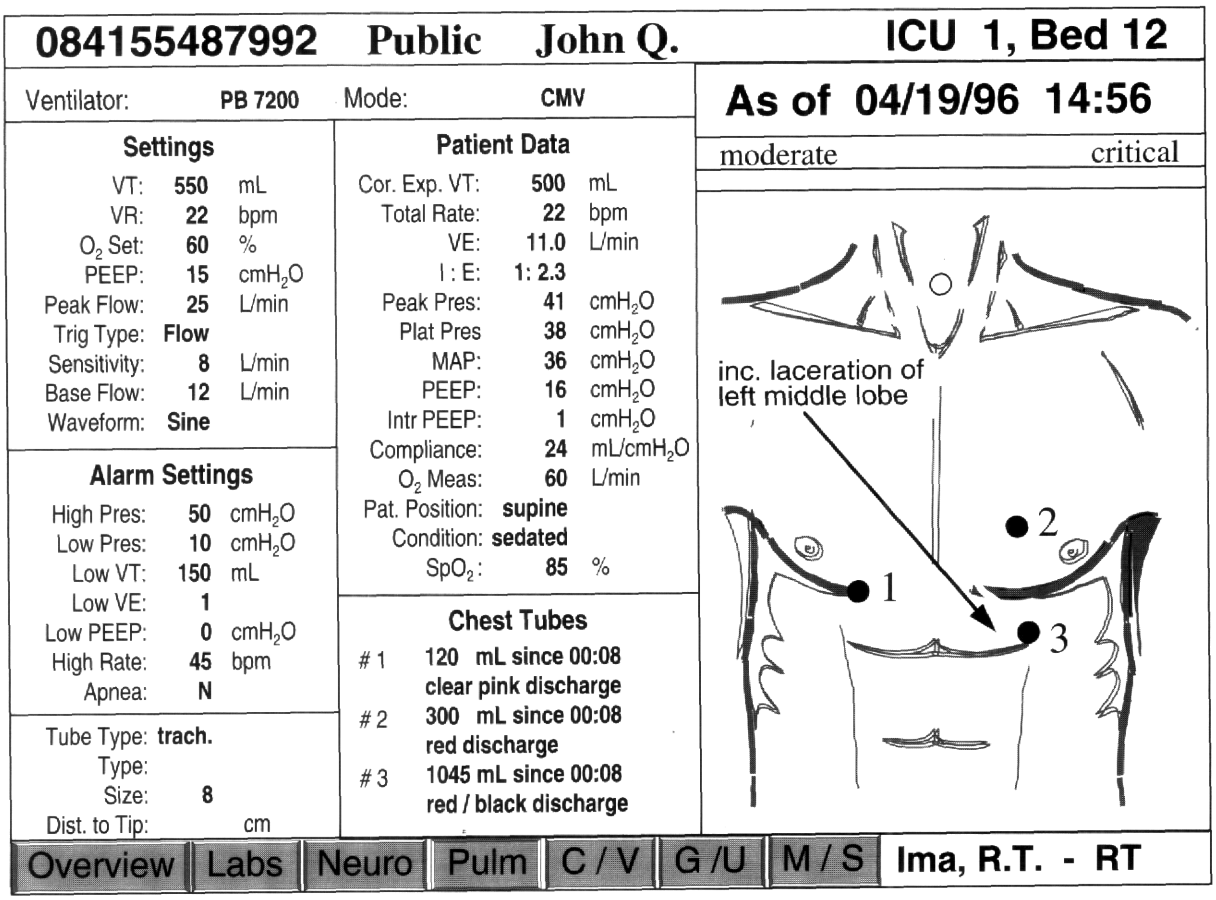


Figure 5.10b – Pulmonary screen for a respiratory therapist. The numbered circles correspond to the three chest tubes; the unlabeled circle in the neck represents the tracheostomy tube. Copyright 1995, Intermountain Healthcare Inc.



No matter what type of interface a CIS uses, it still must fulfill three primary and overriding functions:

1. Provide effective, correct, and efficient data entry,
2. Provide effective and efficient data review, and
3. Not hinder the clinician with its features or problems.

The best interfaces are usually the least complex, and are always the easiest to use.

5.3.5 Tools for Decision Support

Decision support is the use of the computer, at the point of care, to help the clinician make decisions about patient management. Tools for decision support must provide assistance on four levels: 1) seamless access to information systems such as bibliographies (Medline), on-line reference, and training materials; 2) alarms and alerts; 3) expert systems; and 4) closed loop control.

5.3.5.1 On-line Access to Reference and Training Materials

The National Library of Medicine (NLM),[82] as well as several other integrated advanced information system (IAIMS) research sites, have been working hard on integrating reference material such as MEDLINE (accessed through tools such as GRATEFUL MED), and even full text references into the everyday work environment of the hospital. It has been suggested that eventually there would be context-sensitive searches issued automatically by information systems.[83] For example, if the clinician is currently examining data from mechanical ventilation, the computer could issue a query for current references explaining the interpretation of the data and potential therapies. If the clinician needed help at any point, he/she could push a button and get both text and graphic information. There could be an integration of the training and teaching process at the bedside. For example, if the clinician was reviewing a flow-volume loop on the computer and wanted more information on the interpretation, the computer could retrieve the latest journal articles for review, and then enter into a hypermedia training program that would describe, at the user's discretion, many different levels of pulmonary function measurements and interpretation. The hypermedia might include color images of devices and anatomy, typical auscultation sounds, graphs and text. This type of computer-based learning is not new,[84, 85] and the advantages of such learning as an independent learning modality were highlighted in the recommendations of the Association of American Medical Colleges' 1984 report of the Project Panel on the General Professional Education of the Physician and College Preparation for medicine (GREP).[86] The National Board of Medical Examiners has also begun to embrace computer-based testing (CBT) as a method of evaluating fitness to practice medicine.[85, 87] In fact, such systems have already been designed for teaching pulmonary auscultation,[88] blood gas and acid/base interpretation,[89] diagnosis of chest pain,[90] diagnosis of acute respiratory failure,[91] airway management,[92] and a general model of the pulmonary system known as MacPuf.[93] Although the effects of these systems are inconclusive in demonstrating that computer-based learning is better than traditional training, this field is still in its infancy, and it is commonly believed that learning at the "point of care" will be far more valuable than traditional lecture and book formats.

5.3.5.2 Integrated Alarms and Alerts:

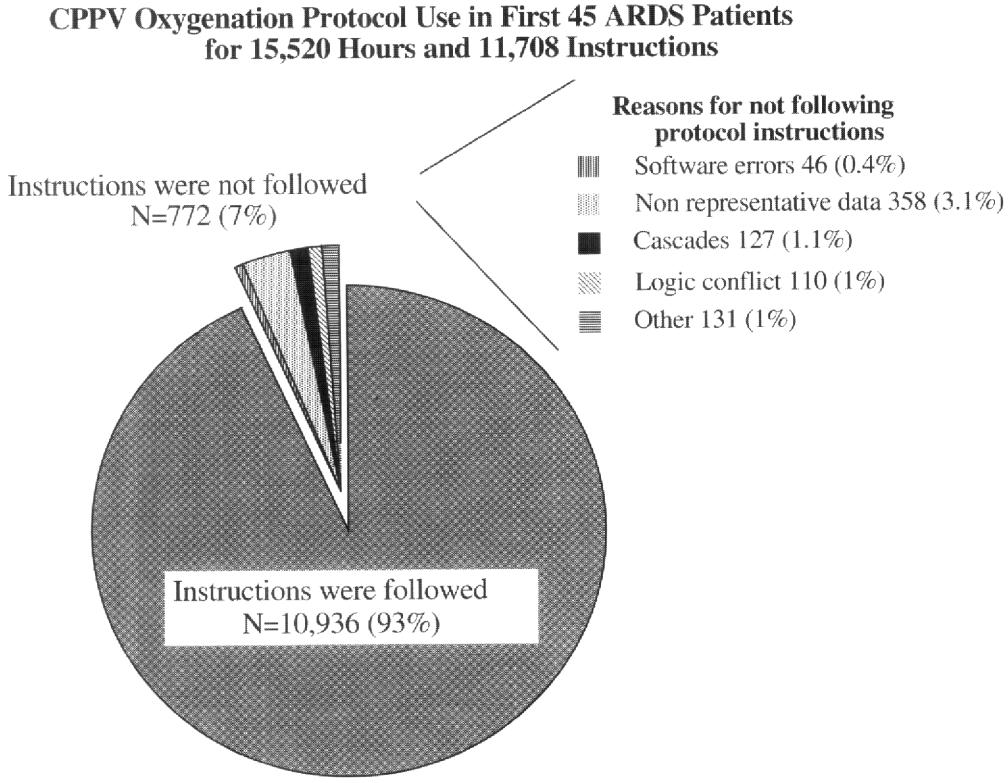
Both the HELP system at the LDS Hospital, Salt Lake City, UT, [8, 94-99] and the PDMS system at Cedars-Sinai Hospital in Los Angeles, CA, provide alarms and alerts.[97] Automated alarms and alerts that are generated on a wide variety of different types of data can help to direct decision making. At the LDS Hospital, alarms and alerts are generated for drug allergies, drug-drug interactions, drug selection and dosing,[100-104] blood ordering,[105-107] infectious disease surveillance,[96, 101, 108, 109] and organ dysfunction or critical changes in laboratory or physiologic parameters.[8, 44, 95, 96, 98, 110] The alerts are automatically generated every time a new piece of information is entered into the system that meets the alert criteria. It is essential to have an integrated database that includes more than ICU data to adequately perform these functions. For example, a respiratory care manager's alert is generated when nosocomial infections are noted in different patients served by the same respiratory therapist.[111, 112] The respiratory care department manager can then review proper policy and procedures with the therapist in the hope of reducing nosocomial infections in the future. This particular example requires data from respiratory care charting as well as lab data from microbiology. Other examples of respiratory care alerts include high endotracheal tube cuff pressures, high PEEP exposure, high FiO_2 exposure, and carboxyhemoglobin present in a patient receiving oxygen (indicating that they are smoking while receiving oxygen). There is a high benefit-to-cost ratio for such alerting systems.[100, 105, 106]

5.3.5.3 Expert Systems

Expert systems are collections of knowledge represented in the computer in a variety of different ways. The knowledge may be represented as a set of rules such as "if A>2 then do B" or it may be represented as a Bayesian probability "if A>2 then there is a 60% probability of B." The concept of expert systems is not new, and medical expert systems have existed for over 20 years. Figure 5.11 illustrates the function of an expert system.[113] The heart of the system is the inference engine (machine shown in Figure 5.11). This engine takes data from the database and rules from the knowledge base, and from these, delivers the inferences. The knowledge base contains the medical rules, heuristics (rules of thumb) and facts.

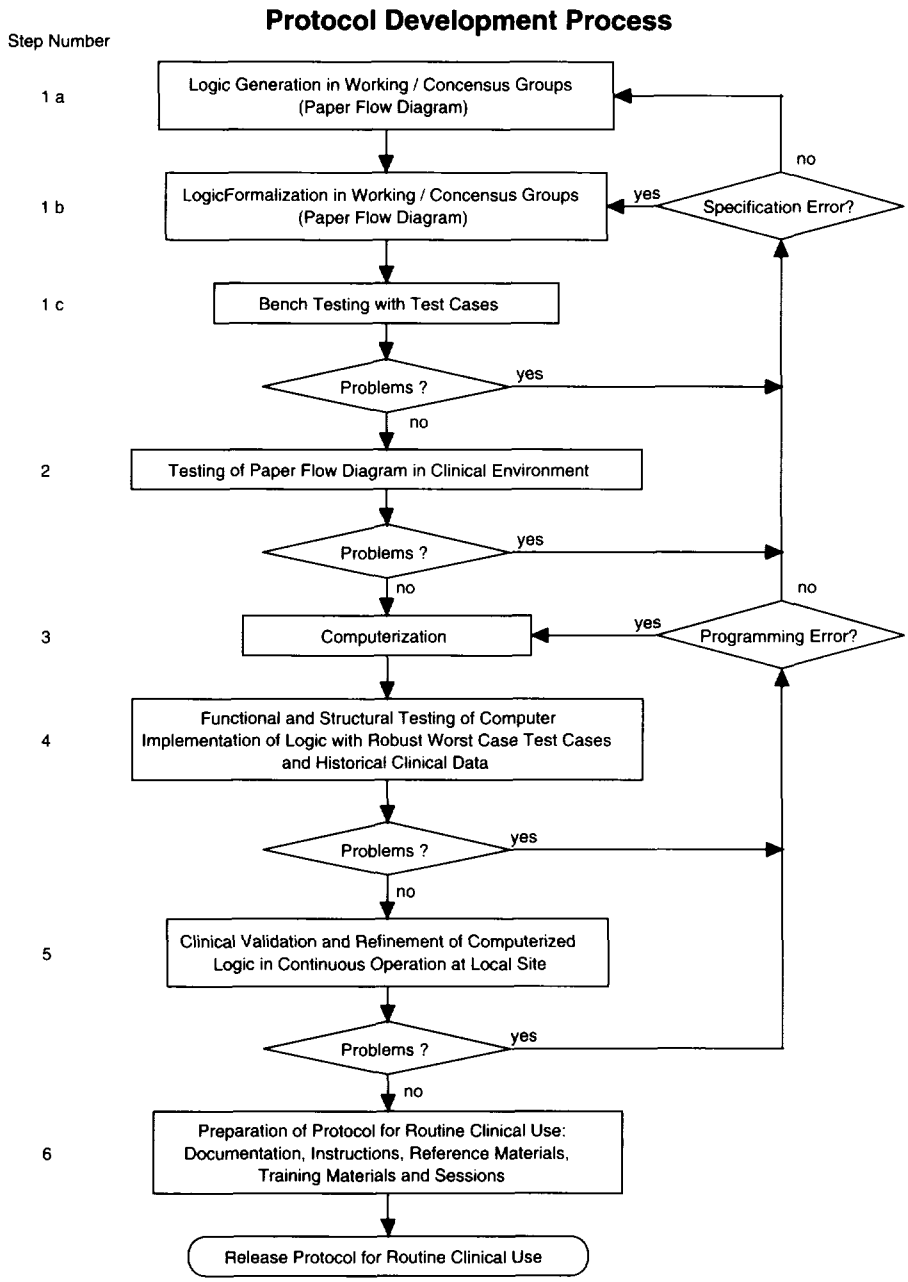
To build knowledge bases, there must be a knowledge acquisition process, often known as knowledge engineering. Knowledge engineering is almost always an iterative process in which the expert delivers his/her perspectives on the problem of interest, and the knowledge base developer, or knowledge engineer, distills from these perspectives a set of rules.[114, 115] These rules are then tested for safety against test cases and for accuracy against both test cases and the expert's decisions.[116, 117] If discrepancies are found, the knowledge base is adjusted until the expert is satisfied with the result. Knowledge bases should not be judged solely on their agreement with the expert on whom their rules are based, but also on their impact on patient care or diagnostic accuracy.[118, 119] In all cases, an independent evaluation of the expert system must be made.[118, 120] Figure 5.12 illustrates the development cycle we have formalized from our experiences.

Figure 5.16 – Specific reasons for the clinical staff not following the protocol-generated instructions in the first 45 ARDS patients cared for using the CPPV oxygenation protocol.



The specific reasons for the clinical staff not following instructions are described in Figure 5.16. The most frequent reason given by the staff for not following instructions was incorrect or inappropriate respiratory care (typographical errors or neglected charting) or blood gas data (due to inappropriate sample handling or a sample taken during a non-steady state) resulting in an incorrect instruction (358 out of 11,708 total instructions, or 3.1%). Only 110 instructions (1%) of the total instructions were not followed because the clinical staff challenged the medical logic of the protocols. The success of these CPPV oxygenation protocols clearly indicates the feasibility of using expert systems for direct management of care for critically ill patients. The physicians, respiratory therapists and nurses commented that the computerized protocol, which acted as "standing orders", simplified management of mechanical ventilation. The CPPV oxygenation protocol is now in routine clinical use for ARDS patients.

Figure 5.12 – Iterative knowledge base and protocol development process.



In all cases, decision support aids should adhere to some sort of published standard. Whether the standard is vendor-specific or from a national or international standards organization is not important, but by using a published, standard format, such as Arden Syntax,[121] the vendor allows the customers to develop their own expert systems without directly involving the vendor. Adherence to published standards also allows vendors to reduce development and training costs. Common knowledge base formats encourage the development and sharing of expert systems and allow the effort to focus on the knowledge rather than on the tools.

In general, expert systems fall into two categories: diagnostic, those which assist or make medical diagnoses or classifications; and therapeutic, those which direct or carry out patient therapy.

- Diagnostic expert systems: Pulmonary diagnostic expert systems have been developed for interpretation of blood gas data.[122-127] Hingston et al. illustrated that while 61% of the participants at medical grand rounds felt that they knew how to interpret blood gas data, and 71% felt that an expert system was unnecessary, the audience was only able to answer 39% percent of the questions correctly.[125] This type of study indicates that despite perceptions, clinicians are not capable of remembering everything in infinite detail and that bedside decision support may be an important asset. Other diagnostic systems in respiratory care include a system for community-acquired pneumonia,[128] occupational lung disease,[129] interstitial lung diseases,[130] and detection of breaths from flow and capnography data.[131]
- Therapeutic expert systems: Several different expert systems have been developed for ventilator management.[115, 132-146] These expert systems can be divided into those designed for general management of the mechanical ventilator[115, 132-143] and those that are designed specifically for weaning.[144-146]

At the LDS Hospital in Salt Lake City, UT, the development of expert systems for management of mechanical ventilation was originally stimulated by investigative needs of a clinical trial of extracorporeal CO_2 removal (ECCO2R) for patients with ARDS.[147-150] The intent was to develop protocols to standardize therapy[13, 51] that could be used by the routine clinical staff. It was reasoned that standardization of therapy would increase the interpretability and credibility of our clinical trial results.[150] The protocol-control goals were to ensure uniformity of care, equal intensity and frequency of monitoring, consistent decision making logic, and common therapeutic goals (e.g., PaO_2). Protocols were developed for volume control (CPPV), pressure control inverse-ratio ventilation (PCIRV), low frequency positive pressure (LFPPV), $ECCO_2R$, intermittent mandatory ventilation (IMV), and continuous positive airway pressure (CPAP) for application in patients with ARDS.[51, 138, 151-153] A special protocol was developed for management of ventilation and intrinsic PEEP for PCIRV.[51] After completion of the clinical trial in 1991, new protocols were written for ventilation and pHa control.[138, 151-153]

The protocols were developed using an iterative build-test-refine cycle (similar to Figure 5.12) that used the clinical environment as an integral part of the development process.[115, 154] It was felt that this was the only way to generate a successful protocol that would handle the majority of circumstances encountered and be acceptable to the clinical care staff. A therapy consensus committee initially consisted of 14 physicians, 3 nurses, 1 respiratory therapist and 1 Ph.D. in medical informatics.[51] This com-

mittee developed and refined protocol logic. All physicians agreed to forego personal treatment style and accept the consensus recommendations that were incorporated into the protocol logic.

The operation of the protocols is demonstrated in Figure 5.13. The protocols are automatically started whenever a new pulse oximeter saturation (SpO_2) or a new PaO_2 is entered into the computer. The protocol first classifies the arterial oxygenation into one of five categories: threatening hypoxemia, marginal hypoxemia, acceptable, satisfactory and supersatisfactory. This protocol also determines the appropriateness of using the SpO_2 to do this classification. In the "gray" areas between SpO_2=75 and 91%, there are specific rules that dictate whether a PaO_2 must be measured to accurately classify the arterial oxygenation.[155] The protocols are automatically activated by the new arterial oxygen classification. The protocol determines whether the patient needs a therapy increase, requires a therapy reduction, or needs to wait without a change in therapy.

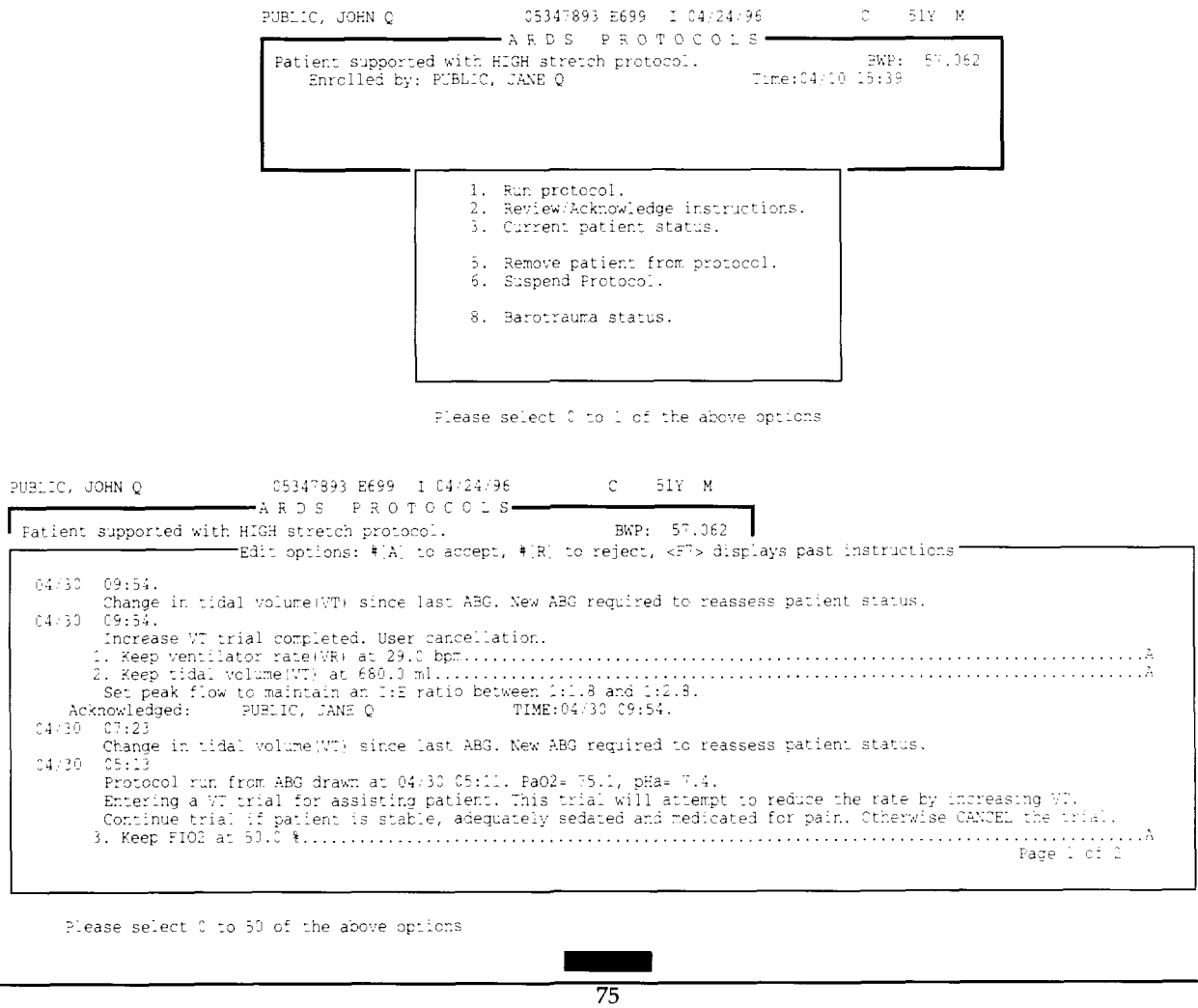
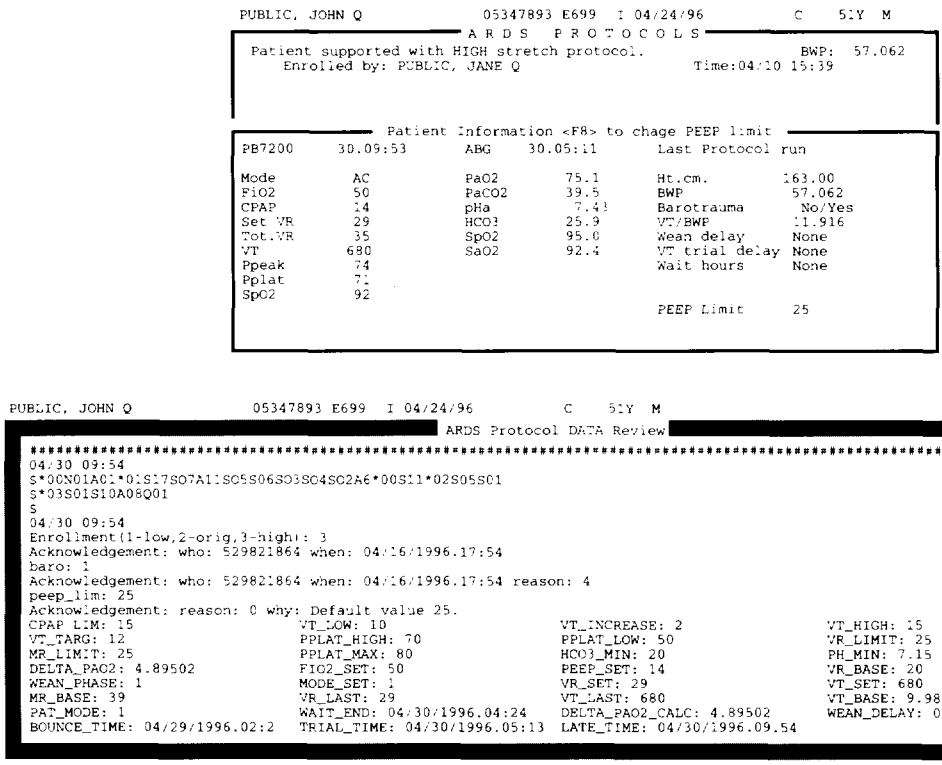


Figure 5.13a – Adult Respiratory Distress Syndrome (ARDS) ventilator management protocol screens from LDS Hospital. The main protocol menu. Copyright 1995, Intermountain Healthcare Inc.

Figure 5.13b – An instruction review / acknowledge screen (option 2). Copyright 1995, Intermountain Healthcare Inc.



```
PUBLIC, JOHN Q              05347893 E699  I 04/24/96          C    51Y  M
                          A R D S   P R O T O C O L S
 Patient supported with HIGH stretch protocol.                        BWP:  57.062
    Enrolled by: PUBLIC, JANE Q                          Time:04/10 15:39

                    Patient Information <F8> to chage PEEP limit
PB7200      30.09:53        ABG     30.05:11        Last Protocol run

Mode          AC            PaO2        75.1        Ht.cm.          163.00
FiO2          50            PaCO2       39.5        BWP              57.062
CPAP          14            pHa          7.43       Barotrauma        No/Yes
Set VR        29            HCO3        25.9        VT/BWP           11.916
Tot.VR        35            SpO2        95.0        Wean delay       None
VT           680            SaO2        92.4        VT trial delay   None
Ppeak         74                                    Wait hours       None
Pplat         71
SpO2          92                                    PEEP Limit       25
```

```
PUBLIC, JOHN Q              05347893 E699  I 04/24/96          C    51Y  M
                          ARDS Protocol DATA Review
##########################################################################################################  1
04/30 09:54
S*00N01A01*01S17S07A11S05S06S03S04S02A6*00S11*02S05S01
S*03S01S10A08Q01
S
04/30 09:54
Enrollment(1-low,2-orig,3-high): 3
Acknowledgement: who: 529821864 when: 04/16/1996.17:54
baro: 1
Acknowledgement: who: 529821864 when: 04/16/1996.17:54 reason: 4
peep_lim: 25
Acknowledgement: reason: 0 why: Default value 25.
CPAP_LIM: 15                VT_LOW: 10                  VT_INCREASE: 2              VT_HIGH: 15
VT_TARG: 12                 PPLAT_HIGH: 70              PPLAT_LOW: 50               VR_LIMIT: 25
MR_LIMIT: 25                PPLAT_MAX: 80               HCO3_MIN: 20                PH_MIN: 7.15
DELTA_PAO2: 4.89502         FIO2_SET: 50                PEEP_SET: 14                VR_BASE: 20
WEAN_PHASE: 1               MODE_SET: 1                 VR_SET: 29                  VT_SET: 680
MR_BASE: 39                 VR_LAST: 29                 VT_LAST: 680                VT_BASE: 9.98905
PAT_MODE: 1                 WAIT_END: 04/30/1996.04:24  DELTA_PAO2_CALC: 4.89502   WEAN_DELAY: 04/25/1996.20:05
BOUNCE_TIME: 04/29/1996.02:2  TRIAL_TIME: 04/30/1996.05:13  LATE_TIME: 04/30/1996.09.54
```

These protocols were computerized using the HELP system at the LDS Hospital.[13, 48, 51, 115, 138, 140, 142, 154-157] As shown in Figures 5.13 and 5.14, the computer displays instructions on the terminal at the bedside. A member of the clinical care team, typically the respiratory therapist, reads the instructions and makes the indicated ventilator setting change. This is NOT a closed-loop system. The computer never makes any adjustments of therapy directly. The clinical care team members always have the option to refuse an instruction. If they refuse an instruction, however, they must provide a reason for not following an instruction. The record of these reasons provides critical feedback that permits protocol refinement.

Figure 5.13c – Patient status review screen (option 3). Copyright 1995, Intermountain Healthcare Inc.

```
PUBLIC, JOHN Q          05347893 E699   I 04/24/96          C    51Y  M
                                ARDS Protocol DATA Review
BWP: 57.0625                    VT_CORR: 11.91676           TRIGGER: 2
spo2_in: 92                     age: 42                     gender: 2          ht_cm: 163
ventype: 2                      cohb*in: 1                  mthb*in: 0.8
fio2_in: 50                     fio2_time: 04/30/1996:09:53 peep_in: 14        peep_time: 04/30/1996.09:53
fio2_in: 50                     fio2_time: 04/30/1996:04:50 peep_in: 14        peep_time: 04/29/1996.20:25
fio2_in: 40                     fio2_time: 04/30/1996:04:25 peep_in: 12        peep_time: 04/29/1996.20:05
fio2_in: 50                     fio2_time: 04/30/1996:04:05 peep_in: 12        peep_time: 04/29/1996.18:00
fio2_in: 50                     fio2_time: 04/30/1996:00:11 peep_in: 16        peep_time: 04/29/1996.17:55
fio2_in: 60                     fio2_time: 04/30/1996:00:06 peep_in: 16        peep_time: 04/29/1996.12:05
fio2_in: 60                     fio2_time: 04/29/1996:22:31 peep_in: 14        peep_time: 04/29/1996.12:26
fio2_in: 70                     fio2_time: 04/29/1996:22:25 peep_in: 14        peep_time: 04/29/1996.04:13
vr_in: 29                       vr_time: 04/30/1996.09:53   mr_in: 35          mr_time: 04/30/1996.09:53
vr_in: 29                       vr_time: 04/30/1996.05:38   mr_in: 32          mr_time: 04/30/1996.07:21
vr_in: 35                       vr_time: 04/30/1996.05:30   mr_in: 35          mr_time: 04/30/1996.05:51
vr_in: 35                       vr_time: 04/29/1996.22:25   mr_in: 41          mr_time: 04/30/1996.05:30
                                                            mr_in: 39          mr_time: 04/30/1996.04:06
                                                            mr_in: 35          mr_time: 04/30/1996.02:19
                                                            mr_in: 39          mr_time: 04/30/1996.00:06
                                                            mr_in: 37          mr_time: 04/29/1996.22:25
ph_in: 7.43                     ph_time: 04/30/1996.05:11   vt_in: 680         vt_time: 04/30/1996.09:53
                                                            vt_in: 680         vt_time: 04/30/1996.05:38
                                                            vt_in: 670         vt_time: 04/30/1996.05:30
                                                            vt_in: 670         vt_time: 04/30/1996.22:25
venmode: 1                      v_mode-time: 04/30/1996.09:53
venmode: 1                      v_mode-time: 04/29/1996.04:13
04/30 09:54.
Change in tidal volume(VT) since last ABG. New ABG required to reasses patient status.
04/30 09:54.
Increase VT trial completed. User cancellation.
VR INST: Keep ventilator rate (VR) at  29.0 bpm.
Acknowledgment: who: 528800222 when: 04/30/1996.09:54
VT INST: Keep tidal volume(VT) at 680.0 ml.
Acknowledgement: who: 528800222 when: 04/30/1996.09:54
Set peak flow to maintain an I:E ratio between 1:1.8 and 1:2.8.
```

Figure 5.14 – Function of the Adult Respiratory Distress Syndrome (ARDS) ventilator managment protocols developed at LDS Hospital. Copyright 1995, Intermountain Healthcare Inc.

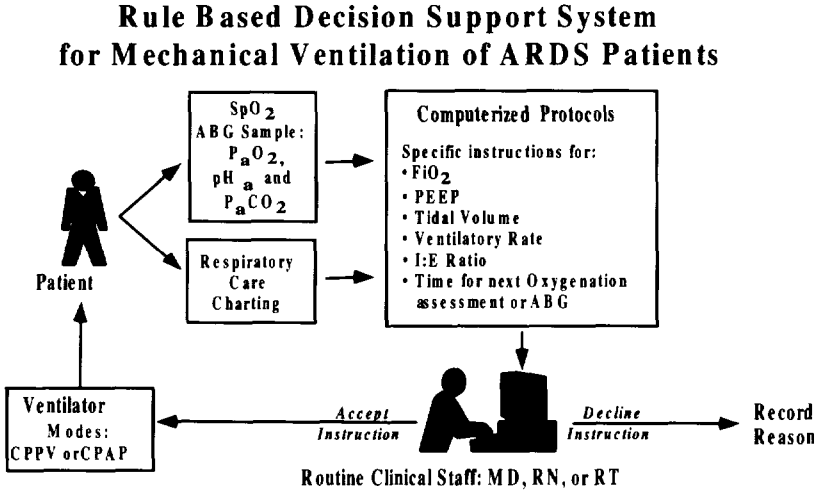


Table 5.5 – Definition of ARDS used in the prospective identification of patients included in clinical trials of the computerized decision support system for management of mechanical ventilations (developed at the LDS Hospital).

Definition of ARDS	
Arterial/Alveolar PO_2 ratio (a/A gradient)	≤ 0.2
or PaO_2/FiO_2 ratio	≤ 200 mmHg
Total static thoracic compliance (CTH)	≤ 50 mL/cm H_2O
Pulmonary artery occlusion pressure (wedge pressure)	≤ 15 mmHg
(no evidence of heart failure or fluid overload)	
Acute onset accompanied by an ARDS risk factor	
Radiographic evidence of diffuse bilateral infiltrates	

The ability of the CPPV oxygenation protocols to control care during around-the-clock application in the ICU was evaluated. The study was approved by the LDS Hospital Research and Human Rights Committee. A total of 111 patients with ARDS were enrolled in the trial. ARDS was defined by the criteria listed in Table 5.5. Detailed data about patient demographics, the use of protocols and patient physiology during protocol use was collected for the first 45 patients. Only outcome data was measured on the remaining 66 patients. Outcome was compared, using a Chi-Square statistical test, to two historical controls; one from the Massachusetts General Hospital (MGH) between 1978 and 1988,[158] and one from the European Collaborative Study.[159] The CPPV oxygenation protocols were applied until patients were weaned to CPAP or died. In the first 45 patients, all instructions generated by the computerized CPPV oxygenation protocol were logged, as was the acceptance or rejection of an instruction by the clinical staff. If an instruction was not followed, the clinical staff member was asked to identify a reason from a menu.[115, 140]

Figure 5.15 summarizes the results of the CPPV oxygenation protocol used in ARDS patients. In the first 45 patients, the CPPV oxygenation protocol was applied for 19±18 (mean ± SD) days (range= 0.2 to 78 days). The protocols controlled care 95% of the time (22.8 hours of the 24 hour day). The protocol was suspended when the patient required transportation to other hospital sites for procedures such as surgery or chest tube placement, diagnostic procedures such as CT scanning, or intense therapy for non-protocol problems such as septic shock.

Figure 5.15 – Summary of the results of CPPV oxygenation protocol use in 111 ARDS patients in the shock trauma ICU at LDS Hospital, Salt Lake City, Utah.

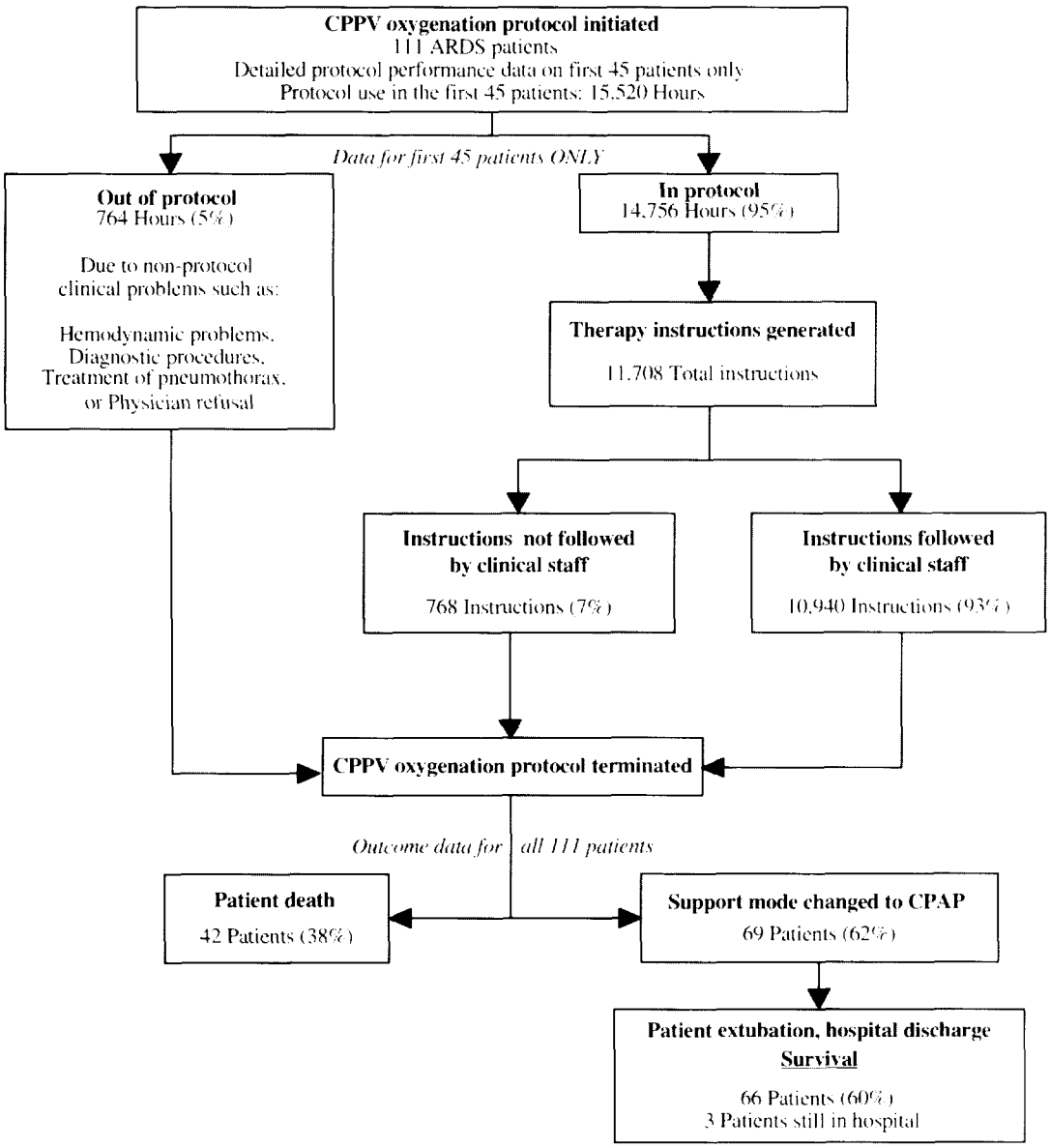
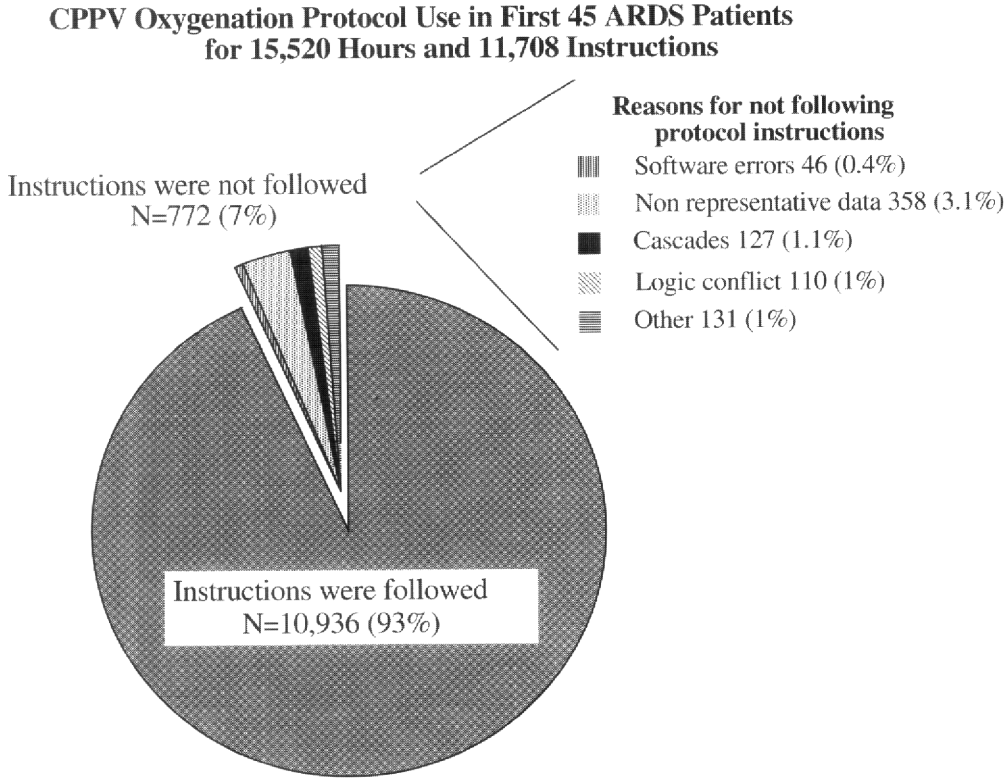
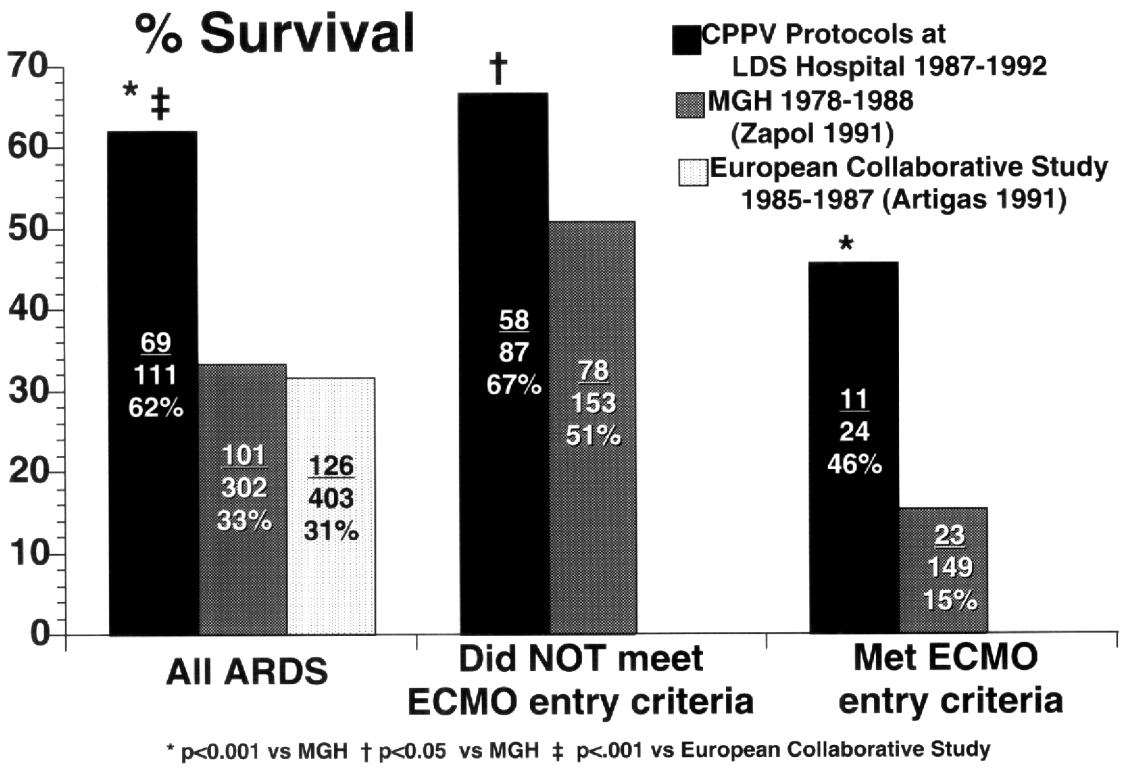


Figure 5.16 – Specific reasons for the clinical staff not following the protocol-generated instructions in the first 45 ARDS patients cared for using the CPPV oxygenation protocol.



The specific reasons for the clinical staff not following instructions are described in Figure 5.16. The most frequent reason given by the staff for not following instructions was incorrect or inappropriate respiratory care (typographical errors or neglected charting) or blood gas data (due to inappropriate sample handling or a sample taken during a non-steady state) resulting in an incorrect instruction (358 out of 11,708 total instructions, or 3.1%). Only 110 instructions (1%) of the total instructions were not followed because the clinical staff challenged the medical logic of the protocols. The success of these CPPV oxygenation protocols clearly indicates the feasibility of using expert systems for direct management of care for critically ill patients. The physicians, respiratory therapists and nurses commented that the computerized protocol, which acted as "standing orders", simplified management of mechanical ventilation. The CPPV oxygenation protocol is now in routine clinical use for ARDS patients.

Figure 5.17 – Survival results for CPPV oxygenation protocol use in 111 ARDS patients in the shock trauma ICU at LDS Hospital, Salt Lake City, Utah.



The survival of patients cared for using the CPPV oxygenation protocol is shown in Figure 5.17. The survival of the whole group was higher than that of similar patients at the Massachusetts General Hospital[158] and from the collaborative European ARDS Study.[159] This difference was statistically significant (CPPV Protocol vs. MGH: $\chi^2_{1\ df}$ =26.5, p<0.001. CPPV Protocol vs. European ARDS Study: $\chi^2_{1\ df}$ =40.0, p<0.001). The survival of the subsets of the 111 patients who met or did not meet ECMO entry criteria was also higher than those published previously[83] (ECMO Entry Criteria: $\chi^2_{1\ df}$ =10.2, p<0.001, Non ECMO Entry Criteria: $\chi^2_{1\ df}$ =4.9, p=0.034).

The mortality associated with ARDS varies widely in the literature. We have chosen two of the largest studies as historical controls. The data from the MGH[158] and the European Collaborative ARDS study[159] are a good summary of the experience both in the United States and Europe in the late 1980s. In addition, the data from the MGH

provided outcome data on patients meeting the ECMO entry criteria, allowing us to compare outcome in the subgroups of severe ARDS (meeting ECMO entry criteria) and less severe ARDS patients (not meeting ECMO entry criteria). As shown in Figure 5.17 the survival of patients cared for by protocol was significantly higher than either of these historical control groups. This was true for all ARDS patients as well as the two subgroups of severe and less severe ARDS. Without randomized clinical trials with concurrent controls, no definitive conclusion can be drawn concerning the impact of protocol control on patient survival. Nevertheless, the outcome of patients cared for by these protocols appears at least as good as the published outcomes. This suggests that computerized protocols can be used to successfully and safely manage mechanical ventilation in critically ill patients. To our knowledge, this is the first demonstration that a computerized decision support system can be used effectively in the critical care environment. Similar protocols could be used in several different arenas: 1) to control future clinical trials as part of the ongoing nationwide effort to determine efficacy of existing and new therapies; 2) to standardize the management of mechanical ventilation, an essential part of the continuous quality improvement process; and 3) to provide decision support in the management of mechanical ventilation for patients with ARDS who are in a variety of settings where a clinical expert in management of ARDS is unavailable.

5.3.5.4 Closed Loop Control

Closed loop controllers are similar to expert systems except that the computer directly adjusts the device of interest without human intervention. Closed loop control systems exist for several ICU processes, including mechanical ventilation and drug delivery.

The technology for closed loop control of mechanical ventilation has been available since the early 1950s. These earlier systems were based on analog control circuits with the first computerized closed loop ventilation control systems being developed during the 1970s. These systems controlled FiO_2 and tidal volume, basing control of ventilation on CO_2 monitoring and maintaining a desired end-tidal CO_2. Few of these early computerized systems were of practical use because of the differences between end-tidal CO_2 and $PaCO_2$ in patients with large physiologic dead space. Closed loop controllers for oxygenation management have also been developed that titrate FiO_2 to maintain a desired PaO_2 or SpO_2. Experimental evidence indicates that, under controlled conditions, these closed loop controllers are better able to maintain oxygenation than humans.[160]

Despite the promise shown by these closed loop controller systems for mechanical ventilation, none have had significant clinical impact. The two primary reasons for this lack of clinical impact are sensor reliability and development environment. While the data from sensors for PaO_2, end tidal CO_2, SpO_2, SaO_2, etc., are reliable for current clinical practices, they lack the accuracy and precision over time necessary for closed loop control. Most of these systems were designed as bench experiments by engineers and scientists, and while they are good exercises, they are not particularly applicable to the clinical practice of medicine.[160]

Closed-loop control has been used to effectively deliver many different types of drugs in both the ICU and OR. Clinical evaluations show these systems are more ef-

ficient and effective at controlling relaxation and blood pressure than most clinicians.[161]

Closed loop controllers for vasoactive medications have been developed, and at least one has been approved for clinical use. These systems are able to rapidly stabilize and maintain blood pressure and perform at least as well as human clinicians when continuous measurement of all affected systems is available.[160, 162-166]

Closed loop delivery of sedatives and paralytics has also been developed. While these systems have performed well in clinical trials, they have not been introduced into routine clinical use in the ICU because of difficulties in placing and maintaining sensors and interpreting sensor results. Clinical studies indicate that both are effective but require clinician supervision because of the monitoring problems.[160]

Because they are more rapid and accurate than the average clinician, and by constantly monitoring and adjusting drug delivery, closed loop controllers have the potential to decrease the workload and increase the safety and efficiency of drug delivery

While cost of these controllers remains quite high, ICU time itself is also expensive which gives closed loop controllers an economical advantage. As in other environments in which closed loop controllers have been used, humans will be required to oversee their safe operation. This job will fall to experienced clinicians who can recognize deviations in care and respond quickly and appropriately.

Decision support tools are not designed to make the experienced clinician obsolete; they are designed to allow the clinician to be a more effective healthcare provider. With healthcare moving more and more toward managed or capitated care, decision support tools will become mission critical components of healthcare delivery. Managed care is pushing clinicians to care for more patients than ever before. Decision support tools, such as expert systems, on-line references, integrated alarms and alerts, and closed loop controllers, will be necessary tools as clinicians strive to improve their delivery of healthcare in the managed care environment.

5.4 SUMMARY

Computers have been a part of critical care medicine for over two decades. Are we better off with computers, or have we merely replaced paper flowsheets with complex computerized flowsheets? The big difference is that now the flowsheets are produced by elaborate computerized systems which cost over $20,000 per ICU bed. The newer systems certainly have the ability to collect and print information with greater accuracy and flexibility; however, there is little evidence to prove that these systems have made a dramatic impact on patient outcome. The next generation of computers for critical care must help the clinicians filter and assimilate the myriad of data and to make fast and effective decisions. This will be accomplished by the use of information systems with integrated, multiview databases, efficient and accurate charting, and decision support tools. These system enhancements will not replace clinical knowledge and experience of working clinicians but will augment their abilities and allow them to provide better care for more patients. It will be essential for all health personnel who are on the "front line" of healthcare delivery to be involved in the creation, testing and implementation of these new systems. The experience at the LDS Hospital has indicated that the integration of the clinical environment into the development process is the true key to success with these systems. The vast majority of the

academic and industrial development going on today involves highly skilled computer scientists and engineers who, through no lack of good will and har work, are not likely to produce anything of value to th clinician at the bedside. We offer this challenge to the clinical community: the future of healthare requires the use of computers at the point of care; it is up to you to get involved and make sure that the end product helps you to improve the quality of patient care while reducing costs.

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6.0 THE ROLE OF CLINICAL INFORMATION SYSTEMS FOR PERIOPERATIVE CARE

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Only four percent of hospitals in the United States have automated any part of the perioperative process. Until recently, this market has gone virtually untouched due to lack of acceptable computer technologies for the confined space in the operating theater and the lack of a simplified user interface. New technologies have the potential to increase the efficiency and effectiveness of the doctor/patient and hospital/patient encounter. This leaves more time for practicing the art of medicine. The use of new technologies that emulate the manual procedures performed by clinicians allows more time for the art of medicine and results in improved quality of patient care while reducing costs. These new technologies have spurred interest in clinical information systems (CIS) for the perioperative process. Clinical information systems significantly enhance outcomes of patient, clinical, administrative, and financial functions in a healthcare delivery system.

While computer solutions for surgical scheduling and surgeon surgical reporting are widely available, clinical information systems for the perioperative process are in their infancy. The perioperative process defined for this chapter includes the care functions provided by anesthesiologists and certified registered nurse anesthetists (CRNAs), circulating nurses and post-anesthesia care unit nurses. This chapter will explore "the need" for information systems for the perioperative process, "the vision" of CIS applications, features and their benefits and "how to" make the vision a reality through successful implementation of a clinical information system.

6.1 *The Need*

About fifty years ago, W. Edwards Deming[1,2] formulated the quality doctrine. Deming's theory, adopted by Japanese manufacturers, was: if quality is built into a product or service, substantial savings would accrue without sacrificing profits. The same principle of quality resulting in lower costs and greater consumer satisfaction was applied to the delivery of healthcare by Berwick[3,4] Wennberg[5], Codman[6], and Shewart.[7] Currently, almost every healthcare provider publicly promulgates their highest priority is to provide high quality and low cost healthcare. The sad truth is that no good measures of quality or costs exist. Vast differences of opinion prevail regarding what is appropriate or inappropriate, necessary or unnecessary, and acceptable or unacceptable when providing healthcare. Some of the reasons for this state of confusion are:

- Lack of sufficient, reliable data
- Lack of validated practice guidelines
- Lack of qualified outcomes assessment measures, and
- Lack of clinical information systems that promote cost-effective, quality care.

For quality to be identified and costs contained during the perioperative process, a long-term database is required. The CIS and its database will be used to differentiate appropriate from inappropriate care, differentiate necessary from unnecessary care, discern practice variances, identify critical paths, determine optimal outcomes and validate practice guidelines. In addition, dysfunctional systems, processes, and structures will be identified. Clinical information systems allow care givers to achieve the coveted goal of substantial savings without sacrificing quality.

A clinical information system for the perioperative process requires a user-friendly computer system, a long-term database and an automated record keeper designed for the day-to-day requirements and processes of the care provider. It must have the capability of incorporating patient, clinical, financial, procedural, management, and knowledge data. It must improve the quality of the perioperative process by improving outcomes, producing a complete, legible patient record and encouraging use of established guidelines and standards.

Anesthesia-related major complications, mishaps, adverse reactions, critical events and dysfunctional systems all may originate in the perioperative period. Mishaps may be the result of human error, equipment failure, lapse of vigilance and distraction. Complications, mishaps and poor quality control are major contributors to the uncontrolled costs in the perioperative period. "An automated information management system can provide answers to service-related questions, dispel misconceptions about prevailing conditions of practice, and track the occurrence of critical incidents (near misses). The ability to quantify critical incidents is an especially powerful tool, as it offers the opportunity to improve outcome by responding to the precursors of complications, not merely the complications themselves."[8] A CIS tracks and identifies the personnel involved in episodes of respiratory arrest, cardiac arrest, myocardial infarction, nausea, shivering, admission to ICU and more. The long-term database can be analyzed and interpreted to identify the techniques with the fewest complications and best outcomes. In this manner quality can be measured, defined and improved. Better quality means fewer complications and lower costs.

A CIS provides a complete, detailed, accurate, and legible document of the perioperative process that can be read by surgeons, nurses and other team members who wish to review the actual objective record. Other members of the care team are not dependent on word of mouth originating from someone who was only remotely involved in the case for accurate information.

A CIS for the perioperative process must be flexible and allow each organization to tailor the system to their established practice guidelines and standards. System protocols can standardize inhalation agents, I/V anesthetics, narcotics, analgesics, and antibiotics to reduce costs and practice variances. Further, the costs of consumables, medications, and fluids could be captured and analyzed to verify practices.

Clinical information systems can amplify corporate understanding and insight into the perioperative period. It provides management the operational data neces-

sary to run an efficient organization. However, accumulating the data is not enough. To ensure quality performance, the clinical database must be analyzed, interpreted and compared by a clinician trained in the discipline being investigated who understands the specific population. In addition, when changes are implemented, their impact must be closely monitored to ensure the expected results are achieved.

Clinical information systems facilitate access to data, reduce costs and furnish information for the measurement of quality and appropriateness of care. When it is all put together, the whole is greater than the sum of the parts because the final result is enhanced efficiency, safety, productivity and performance. Clinical information systems introduce a new paradigm to the delivery of healthcare that stirs the very foundation of modern practice and medical service management.

6.2 *The Vision: Clinical Information Systems for Anesthesia*

The introduction of a CIS into the anesthesia process provides administration, operating room and post-anesthesia care unit (OR/PACU) personnel and the payor with a window into the world of surgery and anesthesia. Before the introduction of a computer system, only indirect information is available. A clinical information system furnishes the information that allows insight into the process, dysfunctions and costs generated during the perioperative period. In this increasingly capitated environment, it is important to be able to determine actual outcomes and costs to gain the ability to manage resources and risk.

A clinical information system for anesthesia must track information through the entire perioperative process (i.e., pre-operative, intra-operative and post-operative). It must allow anesthesia personnel to conduct patient interviews; assess surgical risk; easily record all fluids, medications and agents given during surgery; automatically capture data from the anesthesia monitoring equipment; produce a legible anesthesia record; and provide a database for retrospective review. It will result in a major reduction in paperwork, improve legibility and accuracy, and allow identification of the origin of complications and costs. Additionally, the perioperative clinical information system data repository should allow identification of variances in clinical paths, practice guidelines, and outcomes so improvements can be implemented for clinical and administrative policy. It can be an effective tool to improve quality and reduce costs.

6.2.1 Quality Improvement and Cost Reduction

A clinical information system designed for anesthesiologists and CRNAs would improve quality and reduce costs by providing practice parameters and other applications to reduce patient complications and mishaps.

A perioperative clinical information system can be key to reducing complications and mishaps through two mechanisms: 1) providing functions and features that encourage the use of department policies and procedures, and 2) providing a clinical database repository that allows the retrieval of data for outcomes analysis. A clinical database repository is a long-term database containing clinical, financial and patient

data that allows easy retrieval and analysis of data. The CIS provides the data from which quality can be assessed, defined and improved.

For example, a clinical information system that allows the user to define the medications, fluids and equipment that should be used for each surgical procedure will minimize individual variances and promote usage of materials that have been shown to prevent complications and mishaps. In addition, the database repository will give the department the actual data to quantify the effect on patient outcomes of each user-defined protocol, such as the reduction in the number of nausea and vomiting cases associated with the selection of a particular anesthetic technique, and reduction in the number of admissions that are unplanned. Reduction in mishaps and complications can have a significant effect on cost savings, too. "The ability to reconstruct, understand, and prevent anesthetic incidents and accidents is only one of several good reasons to introduce a system for automated anesthesia records."[9]

Utilizing the data collected during the anesthesia process to determine the most cost-effective treatment, the clinical information system database repository can allow the department to analyze data to determine the optimal anesthetic techniques and agents and balance these with the most cost-effective procedures, guidelines and outcomes. "We have seen a reduction of $20,000 in our pharmacy charges because we can track usage patterns within the department and point out wasteful or needlessly expensive practices."[10]

6.2.2 Freeing Anesthesiologists' and CRNAs' Time for Patient Vigilance

The clinical information system can be designed to collect data automatically from the anesthesia monitoring equipment which will free up personnel from this recording activity and allow them to spend more time at patient vigilance. "Systems may add value in terms of greater patient safety if the system enables anesthetists to take better care of the patients because they are free of a task (completing the record) which would otherwise distract them."[11] In addition, an on-line computer display of continuously captured, multiple monitoring parameters coupled with user-defined "alarms" alerts the anesthesia provider to adverse conditions and allows a proactive response.

6.2.3 Reducing Staffing Costs

With a CIS for anesthesia, traditional manual methods of data collection are no longer needed and staff can be reallocated to other activities. No longer will staff be needed to collect data for JCAHO and other agency requirements, to fill out charge slips or complete the patient chart. "Data gathering and the creation of these reports (required by health regulators and licensing agencies) by hand is tedious at best, unreasonable at worst, and often prone to at least some inaccuracy. Clearly, such tasks by definition are much easier using the output of an automated anesthesia QA system based on the computerized records."[12]

6.2.4 Providing Automated Charge Capture

Without an automated system, charge capture is a manual process that occurs during and after the anesthesia process and as remembered. During crisis, when the patient is the first priority, supplies are often used without being recorded. With a clinical information system, all data for charges are captured automatically and then can be forwarded to the financial system through electronic data interchange.

6.2.5 Reducing Legal Costs

"In the court of law, the quality of the clinical record is frequently taken as a reflection of the quality of the anesthetic care given. Missing data and badly kept records allow conjecture by expert witnesses and reduce the chance that the anesthetist will be defended successfully."[13] A court of law can use the quality of the patient anesthesia record as a key factor in determining the level of care provided. If the patient record is missing data and/or badly kept, the chances that the anesthesia care giver can be successfully defended are reduced. A clinical information system improves the quality of the patient report through automatic capture of data from the monitoring equipment as well as making it easy to record all medications, fluids, anesthetic techniques, events, notes and other information as it occurs, thereby reducing the liability of the organization when a legal situation is encountered. In addition, a CIS can encourage usual and customary anesthesia practice. During the anesthesia process the care provider can record all actions that were taken according to defined policies and procedures (e.g., the patient was identified, all equipment was checked before anesthesia began, an event occurred and the recommended protocol was followed). The CIS can provide the data that verifies that accepted practices were followed during anesthesia which minimizes the risk of losing a court case based on violations of accepted practices.

6.2.6 Required Application Features

In order to achieve the quality improvement and cost savings that can be attained with a clinical information system for anesthesia, a system must provide the applications that make this possible. The clinical information systems that are designed for anesthesia are in their infancy and do not address all functional activities required to achieve the benefits described above. A vision of the clinical information system for anesthesia includes the following functions and features.

6.2.6.1 Pre-operative Care

- Ability to customize the pre-operative data elements to the department's procedures
- Efficient entry of the complete pre-operative patient history and clinical status at the point of care (e.g., patient demographics, surgical information, previous history, bodily systems evaluation, pertinent laboratory and radiology information)
- Ability to enter the risk assessment, assessment reasons, the anesthesia plan and summary of findings

- Ability to bypass the pre-operative evaluation when an emergency occurs and record the reasons the usual pre-operative process was not followed

6.2.6.2 Intra-operative Care

- Assurance that the pre-operative process is complete with the ability to review the pre-operative information any time during the intra-operative process
- Ability to customize the recommended medications, fluids, anesthetic techniques and processes by surgical procedure
- Ability to define which vital signs are to be transmitted and displayed on the CIS monitoring screen
- Ability to record any delays in the start of the procedure and the reason for the delay
- Allows easy recording of positive patient identification, equipment checks, vital signs, medications, fluid input and output, supplies, comments and other information with the ability to edit until the procedure is complete
- Allows recording of all information regarding an activity (e.g., for medications the dosage, units, route of administration, patient response and any adverse reactions)
- Automatic capture of vital sign data from the monitoring equipment with the ability to delete, edit or comment on artifacts as defined by the user
- Data compatibility with point-of-care devices for integration of results and ability to display test results for easy review by the anesthesia care giver
- Automatic recording of all start and stop times for anesthesia and surgery events
- Data compatibility with laboratory information system and ability to display test results for easy review during intra-operative care
- Provides the review of pertinent data on a single screen to permit quick assessments of trends in the patient's condition
- Expert rules-based system that allows definition of alarm limits, warnings, drug dosage calculations and practice parameters
- Ability to efficiently access practice guidelines during the intra-operative process and document the review and compliance during the anesthesia process

6.2.6.3 Post-operative Care

- Allows efficient recording of all post-anesthesia information (i.e., vital signs, color, orientation, consciousness, etc.)
- Ability to record evaluations and complications
- A complete and legible patient anesthesia record according to a user-defined format that includes the entire anesthesia perioperative process

6.2.6.4 General Features

- Compliance with user and manufacturer-based regulatory requirements
- Provides a user-defined security system that only allows access to qualified users and to the data for which they have privileges
- Includes a context sensitive help system

- Integrates with other department systems such as surgical scheduling and laboratory information
- Integrates with other department clinical information systems
- Captures all billable items with electronic transfer to the financial system
- Automatic updates of the clinical database repository which is a relational database that has complete flexibility for user queries and report definition allowing outcomes assessment, practice parameter verification and research

6.3 *The Vision: Clinical Information Systems for the OR Circulating Nurse*

In the majority of healthcare institutions, the OR circulating nurses perform their jobs with little or no computer assistance. Some use bar code readers to scan consumable supply labels after the procedure is completed for partial charge capture, or use systems that allow definition and look-up of surgical protocols, but in most instances the OR nursing record is manually kept. A clinical information system can effectively automate the circulating nurse activities. It can track and capture all patient, room, physician, nursing and concurrent scheduling activities that occur prior to, during and after surgery. It can allow the department to efficiently collect information and accurately charge for the surgical process. More importantly, the circulating nurses will no longer have to scramble before and during surgery to locate the surgeon's individual "case or reference cards" when problems regarding procedures and setups arise. The cards will be immediately available on the CIS in the OR.

6.3.1 Quality Improvement and Cost Reduction

In addition to the benefits of providing an automated charge capture and data collection process during surgery, a clinical information system designed for the OR circulating nurse can improve quality and reduce costs.

6.3.1.1 Reducing Staffing Costs

A clinical information system for the circulating nurse can reduce staff costs with effective supply monitoring to meet surgical requirements. Prior to the next day's surgery, the CIS can be used to monitor the availability of supplies and equipment for the scheduled procedures and any deficiencies can be rectified by either obtaining the needed supplies or rescheduling to minimize delays due to equipment availability. The frequency of surgical delays prior to and during surgery to get the appropriate supplies and equipment will be reduced, optimizing personnel and room usage.

6.3.1.2 Reducing Room Preparation Time and Ensuring Proper Setup

A CIS for the circulating nurse can provide automatic notification of people, room and equipment protocols per surgeon, allowing the OR circulating nurse to quickly prepare the surgical suite with the right configuration, equipment and supplies. In

addition, a Supply Monitoring system integrated into the CIS allows the circulating nurse to identify the location of all equipment and supplies therefore allowing them to easily find all needed items.

6.3.1.3 Reducing Legal costs

A CIS provides improved documentation of the surgical process that helps compliance with OR policies and procedures. Efficient documentation can also provide the necessary support required in case of litigation.

6.3.1.4 Improving Surgical Suite Utilization

A CIS for the circulating nurse that is integrated with the department's scheduling system can provide easy two-way communication between the surgery scheduling center and the OR suite. This communication mechanism can be used to notify the scheduling center of the surgical progress and expected completion time as well as notification to the OR suite of schedule changes that affect the personnel or equipment in use. This streamlined communication mechanism improves the department's ability to efficiently manage the daily patient flow through the surgical department and improves room and personnel utilization, reduces wait times and improves room turnover.

6.3.1.5 Reducing Patient Complications and Mishaps

A clinical information system can be key to reducing complications and mishaps by providing features that encourage the use of department procedures and providing the mechanism to store and easily retrieve data captured during the surgical process. The CIS should have the query and report writer capabilities that promote data analysis to identify the reasons and implement corrective action for mishaps, errors and adverse events that occurred during the surgical process. In addition, the data could be used to define and monitor the practice guidelines to improve patient outcomes. To maximize the benefits of data retrieval and analysis, the clinical database repository should include data from all clinical information systems (i.e., systems used by anesthesia providers, circulating nurses and personnel providing care in the PACU).

6.3.2 Required Application Features

In order to achieve the quality improvement and cost savings that can be attained with a clinical information system for the circulating nurse, a system must provide the applications that make this possible. The clinical information systems that are designed for the circulating nurse are in their infancy and do not address all functional activities required to achieve the benefits described above. A vision of the clinical information system for the circulating nurse includes the following functions and features.

6.3.2.1 OR Processes

- Interfaces with the department's surgical scheduling system to define the demographics of a case
- Improves room set-up by providing notification and checklist of the room configuration, equipment, supplies, medications and fluids required for the scheduled procedure and surgeon
- Allows recording of when the patient reaches the surgery holding area and is ready to be moved to the surgical suite
- Allows the streamlined capture of positive patient identification and verifications for procedure, procedure site, signed consent, special instructions and surgeon
- Includes the ability to easily record the personnel attending the surgery
- Facilitates recording of equipment, supplies, medications and fluids as they are used during the surgical process
- Efficiently captures the surgical process through user-defined nursing flow sheets allowing entry of nursing notes, sponge counts with documented surgeon notification and surgery progress
- Provides a bi-directional interface to the laboratory information system to allow ordering of laboratory tests and blood products with subsequent display of critical results
- Provides the mechanism to easily record delays and mishaps with reasons
- Facilitates communication between the OR control center and the surgical suite for notification of progress and scheduling changes
- Produces a complete and legible patient surgical OR report when the process is completed with automatic notification to the OR control center
- Records the clean-up personnel and time
- Provides the ability to record physician comments and complaints

6.3.2.2 OR Management

- Centralized management monitoring of the activities in all surgical suites
- Allows monitoring of supplies and equipment needed for the next surgical period
- Management and quality assurance reports for turnaround statistics, utilization of rooms, supplies, medications and fluids, staffing activity and procedure statistics
- Quality assurance reports to monitor and investigate incidents and perform outcomes assessment

6.3.2.3 General Features

- Must meet all user and manufacturer regulatory requirements
- A user-defined security system that only allows access to qualified users and to the data for which they have privileges
- Context sensitive help system
- Interface with other systems such as surgical scheduling, laboratory, radiology and pharmacy information systems

- Complete capture of all billable items with automatic transfer to the financial system
- A clinical database repository with a relational database that has complete flexibility for user queries and report definition allowing outcomes assessment, practice parameter verification and research

6.4 *The Vision: Clinical Information Systems for the PACU Nurses*

Personnel in the post-anesthesia care unit (PACU) are closely monitoring the patient through the recovery process. Most complications from surgery appear while a patient is in PACU. The sooner and more effectively the PACU personnel can respond to complications and critical events, the more cost-effective the treatment will be while also improving the patient's experience with the organization. In most organizations, PACU personnel are distracted from their vigilance of the patient by their need to manually record patient data and their need to review manually prepared charts from the surgery/anesthesia process. A clinical information system for the PACU must collect data through admission to and discharge from the PACU. It must also provide easy access to the anesthesia record and the OR circulating nurse record for continuity of care. It must easily capture the fluids used in the procedure, medications administered, automatically capture data from the monitoring equipment and produce a legible PACU record. In addition, the clinical information system data repository, ideally integrated with other department systems, should allow identification of variances in clinical paths, practice guidelines and outcomes so quality improvements can be implemented.

6.4.1 Quality Improvement and Cost Reduction

Improving the quality of care through the entire perioperative process directly correlates to reduced costs. We have already discussed the benefits of clinical information systems for anesthesia providers and the circulating nurse. A clinical information system for the PACU completes the automation of the perioperative process. It provides the following quality and cost benefits which were previously described:

- Provides practice parameters and other applications to reduce the effect of complications on patient outcomes
- Allows PACU providers to spend more time at patient vigilance
- Reduces staffing costs
- Produces a complete and legible patient record
- Automates charge capture

6.4.2 Required Application Features

In order to achieve the quality improvement and cost savings that can be attained with a clinical information system for PACU, a system must provide the applications that make this possible. The clinical information systems that are designed for PACU are in their infancy and do not address all functional activities required to achieve the

benefits described above. A vision of the clinical information system for PACU includes the following functions and features.

6.4.2.1 PACU Processes

- Assures the intra-operative process and records are complete
- Allows easy review of the anesthesia and OR circulating nurse patient records and transfers all relevant data to the PACU patient record (e.g., fluids that have been started)
- Provides the ability to customize recommended medications, fluids and processes for recovery based on surgical procedure, as well as the vital signs to be captured
- Allows easy recording of positive patient identification, equipment checks, vital signs, medications, fluid input and output, supplies, comments and other information with the ability to edit until the recovery is complete
- Allows all information regarding an activity to be recorded (e.g., for medications, dosage, units, route of administration, patient response and any adverse reactions)
- Automatically captures vital sign data from the monitoring equipment with the ability to delete, edit or comment on artifacts as defined by the user
- Accepts data from point-of-care testing devices for integration of testing results and allows easy review by the PACU care giver
- Accepts data from the laboratory information system and displays message of test result availability and allows easy review of these critical results
- Provides the review of all pertinent data on one screen to quickly assess trends in the patient's condition
- Expert rules-based system that allows definition of alarm limits, warnings, drug dosage calculations and practice parameters
- Provides easy access to practice guidelines and electronic documentation when a guideline was reviewed and performed
- Facilitates messaging between the OR control center, surgical suites and the PACU to provide notification of progress and expected arrival in PACU
- Produces a complete and legible patient record according to a user-defined format
- Allows patient satisfaction surveys and assessment to be recorded

6.4.2.2 General Features

- Must meet all user and manufacturer regulatory requirements
- A user-defined security system that only allows access to qualified users and to the data for which they have privileges
- Context sensitive help system
- Interface with other systems such as surgical scheduling, laboratory, radiology and pharmacy information systems
- Complete capture of all billable items with automatic transfer to the financial system

- A clinical database repository with a relational database that has complete flexibility for user queries and report definition allowing outcomes assessment, practice parameter verification and research
- Integration with other department clinical information systems

6.5 Recommended Technologies

Multiple technologies can be offered for successful deployment of clinical information system solutions for perioperative processes. Technology is quickly evolving, and one key to a successful clinical information system will be the design and development of applications that are not tied to a particular hardware and software platform. Ideally, the clinical information system should be designed to capitalize on the evolution of hardware, commercial software and new technologies. Some current technologies that would be beneficial for clinical information systems include:

- Client-server architecture on a local or wide area network
- A stable, proven operating system that functions without errors during critical event capture
- Portable, light-weight workstations for pre-operative and post-operative data recording
- Light-weight, flexible workstation configurations for the data recording at point of care that minimizes space requirements
- Multiple entry mechanisms (i.e., pen, touch, light-pen, barcode reader and voice recognition according to user requirements)
- A commercially successful SQL (structured query language) relational database management system (RDMS) for which query and report writer tools are widely available
- An intuitive, graphical user interface
- Compliance with HL7 standards for easy integration of transactions and interface to other departmental systems
- Fail-safe computer systems

6.6 Making the Vision a Reality

When a clinical information system becomes a priority for an organization and a system has been selected that offers the benefits defined to be advantageous and meets the organization's requirements, an implementation strategy must be deployed. Good project management and the development of a detailed implementation plan are essential for successful system implementation. The implementation plan should include each major task (e.g., hardware installation) refined into each required activity to fulfill the major task (e.g., order hardware).

Task goals:

- Detailed activity descriptions
- Assigned primary responsibility for each activity
- Duration of each activity

- Activity dependence (i.e., which activities can be completed concurrently and which activities require completion of a precursor activity)
- Schedule dates for each activity that take into account the daily number of hours personnel can work on implementation activities

The development of the implementation plan should not be delegated to your CIS vendor. It should be a team effort coordinated through the organization's Implementation Project Manager. After all, no one knows your organization, department, personnel, goals and requirements like you do. The major tasks that should be included in the implementation plan are:

- Implementation team: definition of responsibilities and assignment of a department implementation team
- Hardware implementation: the definition, purchase, installation and test of all hardware, network, and communication equipment along with the operating systems
- Product system definition training: in-depth product training of the CIS's features, functions and user-defined parameters
- Installation of software: installation of the clinical information software on the hardware and testing to insure all features are available as contracted
- Interface implementation: development, installation and testing of all interfaces to monitoring equipment, department systems such as surgical scheduling, laboratory, financial, etc.
- CIS definition: set-up of all user-defined CIS parameters (e.g., medications, nursing flowsheets, personnel, surgical suites, report formatting, policies, practice guidelines, etc.)
- Outcomes assessment: definition and set-up of outcomes assessment and management report requirements
- Procedures: existing departmental procedures for which the CIS will be used should be defined and documented as well as all new procedures required with a CIS such as backups, support, daily maintenance functions, etc.
- System validation and correction: complete system test of all applications following the documented department procedures. (The system validation should be conducted according to a written plan and the validation process documented. Any errors should be processed through the vendor until corrected and any incomplete or unworkable procedures should be changed.)
- User training: complete training of all personnel on the use and procedures of the CIS
- Parallel operations: perform processes with and without the CIS and make system definition, training and procedure adjustments as necessary
- Live with CIS: complete integration of the CIS into the department processes
- Outcomes assessment implementation: use of outcomes assessment processes for the data available with the clinical information system
- Post implementation evaluation: evaluation of the CIS in use, making adjustments as necessary, documenting benefits and comparing against expectations and goals

Good project management coupled with a complete, detailed project plan and an enthusiastic implementation team can successfully implement and derive the expected benefits from a clinical information system. A CIS for the perioperative process will substantially improve access and cut costs while maintaining, measuring and monitoring quality. Using a clinical information system for the perioperative process allows healthcare delivery to be more efficacious, efficient, effective and appropriate.

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7.0 CLINICAL INFORMATION SYSTEMS IN SPECIALTY CARE: THE EMERGENCY DEPARTMENT

by: Vivian West and Ed Naumann

Emergency Departments (EDs) face complex patient care and management issues due to the composition of their patient population and the type of care EDs must be

equipped to deliver. Because of COBRA, a federal mandate which requires hospitals to treat all patients regardless of their ability to pay, emergency departments have become the front-line of care for the many indigent who have no other access to healthcare. As a result of this, emergency departments often serve patients with non-emergency healthcare needs.

According to a 1993 General Accounting Office report, visits to emergency departments increased by 19% from 1985 to 1990, with an estimated 43% of all visits to EDs of a non-urgent nature. Factors contributing to the increase in ED visits include the lack of healthcare coverage for approximately 41 million Americans and increasing prevalence of more serious illnesses and social problems. Moreover, in the United States today, the penetration of managed care in the healthcare environment is changing the role of the ED from its historical "gateway" to acute services to a "gatekeeper" function (referring or sending non-emergency patients to urgent care and outpatient centers).

Information systems can assist care providers in the ED in providing care and tracking clinical outcomes, as well as assist administrators in managing and reporting in a streamlined and effective manner. EDs must be able to capture costs and determine patient insurance coverage/eligibility in order to survive in today's capitated environment and compete with standalone ambulatory/outpatient centers. Increasingly, emergency departments are pressured to demonstrate cost-effectiveness by routing non-emergency cases to urgent care or primary care facilities. They must capture cost and utilization data in order either to charge appropriately for services rendered in a fee-for-service environment, or to contract effectively in a managed care environment.

Hospital administrators have cited the need for clinical pathways and better information systems as top priorities in emergency departments. Costs are also a concern, as administrators struggle to make their EDs more efficient and selective of the patients they treat.

Information systems can help improve processes such as clinical documentation of assessments and treatments, obtaining authorizations, or referrals for treatment. To maximize these benefits, however, the ED must be included as part of an integrated hospital information system. Such an integration can accurately track patient medical information, costs, and dispositions. While only an estimated two percent of the 4,700 U.S. hospitals with emergency departments now use integrated information systems, that number is expected to grow to 20 percent by the year 2000.

This chapter discusses the basic processes found in emergency departments, the way these processes are evolving as managed care continues to penetrate the U.S. healthcare market, and how information technology can enable and streamline these processes and assist EDs in providing quality, cost-effective care.

7.1 Emergency Department Processes

The fundamental processes of emergency departments can be separated into patient care, quality assurance, administrative, and economic. Patient care processes can be categorized according to the progress of the patient within the emergency process (i.e., 1. prior to or at the time of entry to the ED, 2. while in the ED, and 3. after leaving the ED).

7.1.1 ED Entry

Patient care processes prior to or at time of entry to the ED consist of:

- Arrival via ambulance, paramedic services, or walk-in
- Triage (either at the ED, via telephone, or at another facility)
- Medical record tracking
- Patient registration
- Insurance coverage/treatment authorization

If a patient enters the ED via ambulance or paramedic services, there are communication processes occurring between the patient (if the patient is conscious) and the emergency technicians or paramedics, as well as between the paramedics, the emergency facility, and physician. If the patient is critically injured, the paramedics may take the patient to a designated trauma center, where specialized resuscitative, diagnostic, and surgical services exist to treat critically injured patients.

There are three levels of trauma centers: Levels I, II, and III. Levels I and II typically provide comprehensive care to the most severely injured, while Level III facilities are responsible for the stabilization, preliminary diagnosis, and transport of severely injured patients to Level I or II facilities. Although the severity of the patient receiving treatment varies depending on the level of the trauma center, all trauma centers need to have appropriate monitoring systems for their patients, and their information system requirements should not differ between the Levels I, II and III. An exception might be for Level I facilities which are often also involved in research and education and may require certain types of research databases for those functions. Not all emergency departments are designated trauma centers. The other way of entry to the emergency department is when a patient walks in, either through self-referral or by a referral by a primary care physician.

Triaging the patient is a fundamental process within emergency care. Until recently, the majority of triage activity occurred within the ED itself, usually by a registered nurse or physician assistant. This has changed somewhat with the advent of managed care and the move to establish telephone triage for non-emergency patients. Nonetheless, triaging the patient upon entry into the ED remains critical to determining the appropriate level of care and is becoming even more important as EDs refer nonemergency patients to outpatient and urgent care facilities.

Medical record tracking is a key process, and that could be very problematic for the emergency department staff. Often the medical record chart of a patient is not available or there is a delay in locating the chart due to reduced medical records staff after hours. Also, the patient's medical record chart may exist at another facility and not at the facility where the patient is being seen for the emergency service. Information systems can improve the quality of care by computerizing the patient's medical record information and making it possible to share that information across multiple facilities.

Patient registration and insurance authorization are both key processes and have become even more important in a managed care environment. Due to the increased penetration of managed care, providers have a growing need for automation which supports the electronic sharing of demographic and referral/eligibility data. In order to authorize treatments and verify coverage for their patients, many providers

need eligibility data in a more timely manner than in the past. Referral data, both financial and clinical, are critical to ensuring that patients receive high quality continuity of care as they move through delivery systems. Electronic linkages between providers and payers are a vital business need.

7.1.2 ED Activity

Patient care processes while the patient is in the emergency department consist of:

- Patient location/tracking
- Nurse assessment/documentation
- Physician assessment/documentation
- Physician orders/consults/referrals (if necessary)
- Physician treatment
- Patient disposition (admitted, discharged, transferred to other facility)
- Aftercare instructions

Patient location/tracking is of vital importance in the ED. Typically, patient location is tracked manually, either via whiteboards or greaseboards that list the ED bays (or rooms), the patients in each room, and other pertinent data (e.g., provider, chief complaint, and treatment plan outline). Keeping this process manual means that critical ED statistics such as patient wait times, bed availability, and location(s) while in the ED or various ancillaries are not captured for later retrospective analysis. With manual systems, location updates are often not entered for patients transported from the ED to other departments such as radiology or surgery. Also, with the white board system, patient confidentiality could become an issue. Automating the patient location/tracking function can clearly bring many benefits to ED processes.

Assessment and documentation involve taking the patient's medical history and recording vital signs. For the physician, nurse practitioner, or physician assistant, it includes ordering appropriate diagnostic tests and consultations or referrals if necessary. These clinical processes require care providers to refer to the patient's previously documented medical history and to document their own clinical findings. Access to a computerized medical record and the capability to document findings at the point of care would greatly streamline the assessment process for care providers.

Other automation measures could speed up the care process. Interfacing the bedside physiologic monitoring system to the computerized clinical system could completely eliminate manual documenting of vital signs. Computerizing the ordering process could improve the turnaround time for diagnostic test orders and results.

Information systems can contribute directly to the quality of care. They can assist physicians via special knowledge databases, such as poison indices, drug interaction databases, or access to medical databases such as Medline. Advanced clinical decision support tools have shown to be of benefit in acute/ambulatory environments in preventing medication errors and in reducing costs by offering more cost-effective tests as alternatives. Surely their implementation in the ED would benefit care providers there as well. Automating clinical pathways/care protocols would also assist clinicians in the ED in the delivery of care.

Patient disposition and aftercare instructions are the last key processes while the patient is in the ED. Patient disposition includes determining whether the patient will

be admitted to an acute care ward, discharged home, or transferred to another facility. If the patient is to be discharged, aftercare instructions are given to the patient and/or the patient's family on how to care for the patient once at home, what medical follow-up is needed for the patient's medical condition, and how to take prescribed medications. The generation of aftercare instructions was one of the first functions that EDs sought to computerize, in order to streamline the manual efforts involved in compiling these instructions.

7.1.3 Post-ED Activity

Clinical and administrative processes that typically take place after the patient has been discharged or transferred out of the emergency department consist of:

- Case management
- Further clinical documentation/dictation
- Follow-up with primary care physician, referrals
- Patient compliance tracking

In the managed care setting, case management assumes increased importance for acute and ambulatory services as well as those provided in the ED. Another arena that lends itself to computerization is physician dictation of clinical documentation; voice recognition technologies have yet to yield their promise. In addition, computerization offers potential for patient compliance tracking and follow-up, both of which relate directly to clinical outcomes.

In addition to the patient care processes, the ED also must manage quality assurance processes and track quality indicators and clinical interventions such as:

- Mortality
- Return to ED within 72 hours
- Missed diagnosis
- Effectiveness of services
- Illness/injury prevention

Comprehensive information systems can capture these quality indicators as part of the clinical process, eliminating the need for ED staff to manually document and track these data. Outcomes data play a valuable role in demonstrating the quality and effectiveness of care to contracting networks.

Administrative and economic processes that take place in the ED consist of:

- Resource, room, and staff utilization management
- Ancillary utilization
- Charge/cost capture
- Billing
- Patient satisfaction tracking
- Referring physician satisfaction

Automated acuity/staffing systems can turn what is an extremely time-consuming manual process of tying staffing to level of care into a more efficient and reliable pro-

cess. Ancillary utilization, charge/cost capture, and billing systems are essential in both fee-for-service and managed care environments to track costs and collect for services rendered.

By law, EDs are required to generate several reports to meet the requirements of the regulatory agency. Two of the standard reports are the ED log and patient expect log. Both are briefly described below:

- ED logs commonly list all patients (name and identification number) seen in the department, along with arrival time, admission status, workup status, chief complaint, test results, and referring doctor's name.
- Patient expect logs list all patients who are expected (referred by their primary care physician), the time/date expected, and their chief complaint.

In addition, reporting is also required to support the requirements of:

- Trauma registry
- Public health
- Employee health
- State regulatory agencies

Quality indicators such as transfers to other facilities, death rates, and readmissions within 72 hours must also be reported, as well as various cost and charge capture data and provider/facility billing data.

7.1.4 Changes in ED Processes/Operations

Many EDs across the country are enacting operational process changes due to the advent of managed care. These include new triage and clinical protocols, triage transfer procedures and programs, and other innovative new programs. There are no documented numbers as to how many hospitals are restructuring their ED processes due to changes brought about by managed care. However, in a 1994 survey by researcher Leslie Zun, 54% of 131 hospital administrators cited integrating with managed care as their top priority.

Although there are still some disagreements as to the true costs of administering non-emergency care in EDs, recent studies suggest a potential savings in diverting patients to urgent care facilities may be lower than anticipated. Nonetheless, managed care organizations and Medicaid and Medicare reforms are requiring EDs to demonstrate that they deliver cost-effective quality care.

An example of changes in triage programs involves using contracted teams of physicians to triage and oversee emergency care at out-of-network hospitals for managed care patients. These physicians see the managed care patients at the ED and then decide on appropriate care and intervention, which may involve referring the patient to his primary care physician in lieu of admission if, after medical evaluation, the triage team of physicians deems it appropriate.

Other EDs are instituting clinical triage protocols to identify patients with minor illnesses that should not be treated in the ED. Triage nurses use predefined lists of symptoms to decide whether to refer the patient to ambulatory facilities or admit for treatment in the ED. In some cases, facilities with EDs are enlisting support from

other acute care area hospitals to develop common approaches to emergency triage procedures.

As many states convert their Medicaid plans to managed care Medicaid programs, some facilities are restructuring their EDs to better manage patient care and avoid financial losses. Restructuring efforts include innovative programs, such as decentralizing patient registration from the front of the department to patient care areas, setting up 24-hour observation units and chest pain clinics, or opening nearby urgent care facilities. Another innovation is the fast-tracking system, whereby patients already determined to be non-emergency by triage nurses are sent to a "fast-track" area adjacent to the ED that is staffed by nurses who primarily administer less critical first aid.

EDs must respond to increasing pressures to reduce costs while, at the same time, maintain quality of care and serve a diverse population. This challenge, coupled with the complexity of functionality in the ED, makes information systems a critical requirement. Only with robust clinical and administrative/financial systems will EDs be able to improve operating efficiency and track quality and cost outcomes.

7.2 Current ED Systems

There is no universally accepted definition of an ED clinical information system. ED systems can offer anything from the very basic capabilities to comprehensive functionality which meets most of the department's needs. Generally, ED systems fall into three categories:

1. Adaptation of the hospital information system (HIS),
2. Standalone applications (see below), and
3. Comprehensive ED systems.

Each category has its own advantages and disadvantages.

7.2.1 Adapted HIS

The most common approach to ED information systems is to adapt an existing HIS for the special needs of the department. In most cases this approach typically has a low incremental cost since hospitals are already using the existing system in other areas of the hospital. Major HIS vendors are resistant to offer a specific module for the ED, because ED requirements rarely drive the HIS purchase decision. The HIS is usually minicomputer-based with dumb terminals or personal computers as workstations, written in a proprietary language, and often running in a non-open operating system. This makes changing the system more difficult than in an open system, object-oriented environment.

Most hospital information systems offer registration, order entry, results reporting, medical records, and billing functions. Charge capturing functionality is often offered as well or can be added through a third party package. Many hospital information systems are configurable and have the capability for adding user-defined data elements to the system. Screen layouts and flows can also generally be redesigned for the ED's emphasis on STAT orders, quick data entry, and incomplete patient registra-

tion information. It is also common in this situation for an ED to have printers dedicated to printing lab and radiology orders and results so that this information can be handled quickly rather than having to keep checking the system.

While adapting the HIS in this manner can meet many of the basic needs of the department, it generally does not address patient tracking, clinical documentation, discharge instructions, transcription, and the ED log requirements. These requirements often remain manual processes in such situations. If the HIS has advanced clinical functionality (e.g., nursing assessment, documentation, case management, clinical pathways), these features can also be used in the ED but tend to leave shortfalls when compared to comprehensive ED systems.

7.2.2 Independent or Standalone Software Applications

A number of vendors offer standalone systems for the ED. Many of these systems have been around for a long time and are relatively inexpensive, but they rarely interface with other systems in the department such as the HIS. Some of the most common standalone systems in the ED offer patient discharge/after-care instructions, transcription, patient tracking, diagnostic aids, and patient classification/resource management functions.

Patient discharge instruction systems enable the ED to generate after-care instructions to give to patients when they are discharged. These instructions provide patient education about caring for their problem and what follow-up action is required (e.g., return to the ED in 72 hours, referral to the patient's primary care physician). Usually PC-based, these systems require some basic data entry of the patient's name and condition. They help the ED issue accurate instructions without having to maintain file cabinets full of different preprinted forms, thus reducing liability. This function is available in most comprehensive ED systems as well.

Transcription systems continue to undergo technological change. The development of voice recognition capabilities has increased the number of physicians and clinicians who dictate directly to the transcription system rather than to the traditional taping system. Because ED patients without health insurance tend to return to the ED for follow-up care or other medical attention, it is important to have access to transcribed reports as quickly as possible. EDs vary greatly in their level of transcription automation, but this is one of the more likely areas to incorporate voice recognition. This technology remains expensive and can cost $45,000 per clinician workstation. Standalone dictation and transcription systems may make the department slightly more efficient but do not help with the overall case management of the patient. When interfaced to the HIS or a computer-based patient record (CPR), ED transcription systems provide a necessary piece of the patient's medical encounter history.

Patient tracking or patient location systems are generally homegrown PC- or network- based systems which automate the ED greaseboard or whiteboard. These systems basically do little more than display the greaseboard information (e.g., patient location, complaint, resident) on PCs rather than on the single board. Unless it is combined either with the capability to enter ED log data or involves simply adding the application to an existing network environment, there is little cost-effectiveness. Patient tracking is a feature available in all comprehensive ED systems.

Diagnostic support systems provide suggested diagnoses and interventions when given the patient's chief complaint, symptoms, and lab results. These systems assist the clinician in assessing ED patients. Usually operating on standalone PCs, diagnostic support systems require data entry which could mean duplication of work. Diagnostic support systems are popular at teaching institutions. Comprehensive ED systems currently available rarely include this functionality. However, given the trend toward increasingly sophisticated decision support systems in all clinical information systems, comprehensive ED systems on the market may expand their product line to include it, or ED clinicians may integrate a decision support product with the ED system they already use.

Patient classification/resource management systems are prevalent in the ED. These systems capture and analyze workload measurement and productivity information. EDs use these systems to determine staffing needs based on levels and patterns of patient workload. Patient population trends such as acuity, length of stay, and discharge disposition can be captured and used to make decisions. These systems provide management information which helps predict patient demand, determine staffing levels, and track the need for other services (i.e., minor care or urgent care centers). As a standalone product, these systems are usually PC-based and require duplicate data entry. This resource management functionality is included in all comprehensive ED systems.

Another important niche application, often available as part of point-of-care documentation and clinical systems, is medical machine monitoring interfaces. This functionality allows for the automatic download of machine monitoring data (e.g., blood pressure and telemetry readings) to a clinical documentation system, reducing the need to manually re-enter these data into other clinical systems.

While standalone applications exist for many of the ED's unique information system needs, their standalone deployment can lead to piecemeal solutions and duplicated data entry effort. Developing interfaces for these systems can end up costing more to build than many of the niche applications.

7.2.3 Comprehensive ED Information Systems

An alternative to either adapting the HIS or using several standalone systems is to use a comprehensive ED information system. Some of the common features offered by such integrated ED information systems include:

- Triage assessment and documentation
- Registration (or interfacing to the HIS)
- Patient location and tracking (i.e., status boards)
- Order entry (or interfacing to the HIS)
- Results reporting (or interfacing to the HIS)
- Prescriptions
- Transfers/referral notices
- Patient discharge instructions (often in multiple languages)
- Workers compensation (first report of injury, progress, and final reports)
- Automated ED log
- Resource management
- Utilization review

- Comprehensive report writing

Some of the comprehensive vendors offer dictation, nursing notes, clinical and physician assessments and interventions, follow-up clinical documentation, electronic signature, or trauma registry functionality. Most of the standalone vendors are experienced at developing interfaces to the major HIS vendors for admit, discharge, and transfer (ADT) data, patient demographics, order management, results reporting, and charge capture/billing.

Comprehensive ED systems are usually minicomputer or client-server based. They operate in most of the standard network topologies. Programming languages tend to be C, C++, and Visual Basic, with a vendor or two relying on COBOL. Most of these systems have extensive databases to facilitate long-term data retention and studies. Oracle is the most common database manager. Good comprehensive ED systems are modular in nature so that they can be implemented in phases. This expandability enables the ED to deploy the most critical functionality first and implement other modules later.

Comprehensive systems can be expensive; most are in the $150,000 to $500,000 range. This represents a substantial investment for the department. The investment may be very worthwhile considering the growing volume of patients seen in the ED and the increasing need for information technology investment in all ambulatory care environments.

7.3 Emerging Information Systems/Technology

Emerging technologies either are impacting the ED presently or will in the near future. Hardware, communication, software, and linkage/interfacing capabilities will make ED information systems more robust, more cost-effective, and easier to use. These capabilities will be incorporated faster by some vendors than by others.

On the hardware side, ED clinical information systems will become increasingly scaleable as they become more and more client-server based. This will enable EDs to add relatively inexpensive computing power to their systems as needs or volumes increase. There will be a wider number of data entry modes. In addition to the keyboards and mice which are prevalent today, there will be more options for barcode, smart card readers, touchscreens, pen-based computing, and voice recognition. ED clinicians and staff will be able to select the appropriate data entry method for each area or process. Physicians could use voice recognition for dictation; nurses could use touch screens for assessments and interventions; and the registration clerks could use keyboards. The mode of entry should become less and less a barrier to data capture.

Changes in communication capabilities involve three areas: 1) how ED system users communicate with their system; 2) how the ED communicates within its healthcare organization; and 3) how the ED communicates with emergency medical services (EMS), paramedics, and mobile teams. Like other patient care delivery areas, EDs should be expected to make use of hand-held computing devices for communicating between the host system and the point-of-care. These may be radio frequency (RF) or devices which have data downloaded to them at a nursing station. In the ED environment, RF would be preferred because of the frequency of patient location changes and the awkwardness of having to return to a common station for uploading or downloading. Currently, most EDs do not use this type of technology because

hand helds may "walk out the door." As the devices become less expensive and as ED security monitoring is upgraded, this should become less troublesome.

As more healthcare organizations deploy advanced local area networks (LANs) and wide area networks (WANs), it will be easier for the ED clinical systems to communicate and share data with the hospital and clinical information systems. Many organizations are spending significant resources to upgrade their internal communication capabilities by installing Ethernet backbones and enterprise-wide networks. These developments enable users with the appropriate security clearance of a common PC-based workstation to access any appropriate information system on the network. Thus an ED system user on a PC can access the HIS and other systems to get information as needed—saving telephone calls, runner time, and other clerical time.

Developments in distributed architecture and remote communications may enable the ED to share data with EMS, paramedics, and mobile teams. Vitals signs assessments and treatments performed by the emergency care provider could be communicated to the ED clinical system while the emergent patient is in route. Such communication would improve the time an ED has to prepare for a patient, facilitate more accurate charting, and improve quality by providing faster, more appropriate care to the patient. This type of system-to-system communication relies on each party to implement systems and many of these groups do not have much automation today.

On the software side, developments under way will greatly enhance ED clinical systems. The current emphasis on ambulatory care supports the need for such a documentation system. The fact that ambulatory and emergency environments have common needs will allow the ED to adapt solutions developed by ambulatory care system vendors.

Industry-standard tools are changing the way ED systems are developed. Most vendors are using Structured Query Language (SQL) compliant databases which make the data accessible to industry-standard SQL report writers. This will enhance user access to data for best practices, clinical pathways, and other outcomes-related studies. System development in healthcare is evidencing trends that have already occurred in other industries. For example, ED system vendors are writing programs in object-oriented and fourth-generation languages. This will shorten enhancement and development cycles, and vendors will be able to issue new releases of software more often and with more features. ED system vendors will continue to develop Graphical User Interfaces (GUIs) which are more intuitive and much easier for clinicians to use than the existing character-based applications. Also anticipated is increased use of hypertext to provide additional information when requested by a clinician.

The most significant software change on the horizon for ED clinical information systems is the development of expert logic/rules-based decision support. This functionality enables the clinician to interact with the ED system and receive prompts (advice). Expert system support can suggest alternative and possibly more cost-effective interventions and medications, and can remind clinicians of ED protocols, policies, procedures, and other requirements. Rules-based decision support can evaluate any number of factors, for example lab results, medications, and patient history, before suggesting a course of action. This type of capability can be deployed in various forms, from simple rules and reminders to highly complex decision support. If the ED is like other users of expert systems, it will begin using this functionality in a basic, clinician-friendly version and develop additional rules over time.

How ED systems link or interface to other systems continues to improve. The ED needs to share data with a number of internal and external users. Fax servers are available today which can fax forms, discharge instructions, etc. to other physicians in a very user-friendly manner. This "fax on demand" functionality will soon be included in most ED systems; hopefully, it will be expanded to automatically fax data based on certain trigger events. For example, when a patient leaves the ED, the system will fax a copy of the discharge instructions and physician notes to the patient's primary care physician.

But faxing information to primary care physicians, industrial medicine clinics, occupational medicine clinics, and employee health offices is not the same as sharing data between systems. In the managed care environment, where capitation demands the highest level of coordination of care and the lowest level of duplicate effort, ED systems will need to share data directly with systems in other clinics and offices.

Another development which should be anticipated eagerly is a much greater level of interaction between the ED system and outside databases (e.g., poison indices, MedLine, and other knowledge databases). Most of these are standalone products today, just as are most ED information systems. Accessing these databases simply from the ED system would greatly enhance access to and use of the information to improve patient care delivery. Enabling clinicians to access various third party databases from a common ED system encourages them to use the system, provides greater value to the clinician, and leverages the hardware/network investment. In addition, the use of the Internet to offer clinicians access to medical publications and information worldwide will provide value to ED clinicians and staff.

The emergence of digital imaging technology and the increasing deployment of picture archiving communications systems (PACS) in radiology departments in hospitals and diagnostic imaging centers will enable ED physicians to view radiological images via a special high-resolution, diagnostic-quality video display terminal located in the ED. This can enhance the ED physician's care of the patient and facilitate consultation with the reading radiologist. Because of the high cost of video display terminals needed for diagnostic applications, use of picture archiving communications systems have remained limited to few hospitals. However, with prices of computers coming down in recent times, more ED physicians should be able to afford this technology.

Telemedicine and teleradiology technology are trends that will affect EDs and paramedic/ambulance services in the future. The deployment of these technologies will allow both the primary care physician and the ED attending physician to communicate effectively with paramedic/ambulance technicians caring for the patient and with the patient himself (if the patient is able to communicate). Telemedicine technology is still not widely deployed due to cost and reimbursement issues, but will continue to permeate the marketplace as hardware costs and reimbursement issues permit.

The development of application integration systems (AIS) or interface engines will make it easier for all types of information systems to share data with one another. Many healthcare organizations are implementing an AIS to enable their HIS and various departmental systems to share data and eliminate duplicate data entry. The ED system can benefit from this development because interfacing data via an AIS is generally much less expensive than developing point-to-point interfaces. Today, many ED information systems are not interfaced to the HIS because of the high cost involved. Interface engines should significantly lower this barrier to data sharing.

Application integration systems technology also facilitates easier access to an enterprise's clinical data repository and computer-based patient record (CPR). ED system data are an essential part of the patient's lifetime clinical record and need to be included in any CPR strategy. Likewise, the ED can derive substantial benefit by being able to access each patient's historic data. Since the CPR is not a single system or product, but instead a strategy and combination of systems, the exact interaction between an ED information system and the CPR is hard to determine at this point in time. As healthcare delivery systems build their CPRs over the next five to ten years, this interaction should become more structured and more beneficial.

7.4 Conclusion

The information system options available make it possible for EDs to employ information technology in ways suitable to their particular environment, functional process requirements, and budgetary constraints. The increasing pressure on EDs and hospitals to curtail costs and improve operating efficiency while still providing quality patient care makes the successful deployment of integrated or interfaced clinical, administrative and financial systems even more critical than in the past.

EDs are a necessary and socially valuable component of the healthcare delivery system. As managed care continues to penetrate all areas of the country, however, EDs will be required to demonstrate to managed care networks and to their own administrators that they can provide quality outcomes at competitive prices. They will be forced to streamline operations and reduce manual and administrative inefficiencies in order to survive. Information systems can enable and enhance the clinical and management functions of an ED by providing timely and accurate access to patient historical and current clinical and financial data. Linking information systems between providers and payers can improve the triaging, eligibility and referral processing for ED patients. Automated collection and storage of patient data can support research and statistical/management reporting without hours of manual work. In sum, information technology properly used and deployed in emergency departments will assist clinicians and ED staff in attending to their highest priority—caring for their patients.

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8.0 EVOLUTION OF CLINICAL PATHWAYS: ISSUES DRIVING THE NEED FOR AUTOMATION‡

by: Debra Anne Slye, MN, RN

In response to the demands of the managed care environment, healthcare delivery systems are in the process of evolution to support population-based care across the continuum (Table 8.1). Healthcare enterprises are faced with various internal and external incentives aimed at the delivery of improved quality patient care at a reduced cost. In the absence of well-defined indices of quality, cost cutting has become the management target. At the present time, most enterprises lack the data necessary to determine which clinical processes and interventions are the most cost-effective in achieving the desired outcomes. To better manage and drive the care process we need quality information. The volume of data required can be exhaustive and the transformation of that data into information can be overwhelming if relegated to a manual process. Integrating an automated approach is essential to make the process realistic and the resulting information applicable.

Table 8.1 – Evolution in care delivery.

Past healthcare environment	Present healthcare environment
• Acute inpatient care	• Continuum of care
• Treating illness	• Maintaining wellness
• Individual patient	• Accounting for health status of populations
• Fragmentation	• Consolidation
• Fee-for-service	• Fixed, prepaid rates for population
• Revenue-based	• Cost/quality, population-driven
• Patients	• Covered lives
• Fill beds-excess capacity	• Treat at appropriate care level
• Closed systems	• Open systems

‡ Dykes P and Wheeler K (eds). Critical Pathways and Healthcare in the 21st Century. NY: Springer Publishing, In Press

8.1 Management of Patient Care Across the Continuum

Case management is a strategic approach to the management of cost and quality outcomes across the continuum. The overall goal of case management is to proactively move patients through the care process by monitoring expected outcomes, removing barriers to progress, and ensuring appropriate utilization of resources. Most case management approaches involve the use of standardized clinical pathways as a method of enhancing care efficiency and promoting adherence to standards for a given patient population. Experiences in non-healthcare industries have shown that definition of a "best" practice model and adherence to that model reduce unintended variations in practice for a given population. Reductions in variation have been associated with improved outcomes and reduced costs.

Clinical pathways are multi-disciplinary plans of care that outline the typical course for approximately 80% of the cases of a particular type or diagnostic category incorporating critical events and key interventions that must occur in a given time frame and sequence to achieve specific patient outcomes within a predetermined length of stay. Clinical pathways have become an accepted method of guiding clinical practice for individual patients. Through the cross-patient analysis of data extracted from the pathway (i.e., care delivered, outcomes achieved and variances experienced), pathways can serve as a tool for coordinating the care of patient populations.[1] In many care settings, clinical pathways have been shown to improve interdisciplinary communications, encourage timely interventions, improve documentation of care delivered, reduce redundancy in documentation, enhance analysis of outcomes, facilitate concurrent quality improvement, reduce length of stay and contain costs.[2] Information systems are essential for the clinical pathway to be a useful tool in handling clinical data, managing the care process, documenting resource utilization and analyzing cost-effectiveness.[1] If pathways are continuum-focused, they can be effectively used to guide health maintenance and manage disease states in an effort to reduce costly hospitalizations.[3]

8.2 Developing Automated Clinical Pathways

The majority of clinical pathways in use today were developed using the traditional paper-based approach. Once a standard pathway is designed on paper, it can be applied to an individual patient. However, the degree to which a paper-based pathway can be customized to an individual patient is very limited. Paper pathways are often used as reference documents and not as interactive tools to truly manage the care of individual patients. While some enterprises have found creative layouts that support the documentation of care and variances using a paper-based pathway, the data from such paper documentation must still be manually extracted to accomplish the variance analysis necessary to make critical decisions. Some enterprises have developed forms for variance tracking that can be scanned into a computer application for later data extraction. However, even in these cases, care documentation is usually a separate process.

Automating the pathway process greatly enhances the ability to customize a standard pathway to meet the unique needs of individual patients. Advantages to auto-

mating pathways are listed in Table 8.2. Incorporating the real-time patient care documentation as an integral component of the automated pathway brings the standard pathway to the core of the care process, facilitates the care provider's awareness of and adherence to the standard pathway, and automatically generates variances based on the presence or lack of care documentation. To be truly multidisciplinary, the automated pathway should be integrated with the orders management application. As with care documentation, integration of orders into the pathway focuses each care provider on the standard and on how a particular patient is adhering to or deviating from that standard. If a patient is experiencing variances, rationale can be documented and analyzed to determine whether these variances might be avoidable, causative factors might be resolvable, or whether the variance is truly patient-specific and does not warrant any further consideration from a standards perspective.

Table 8.2. – Advantages to automating pathways.

• Timely and accessible information
• Shared data elements eliminates redundant data entry
• Improved information acquisition with integration of various systems
• Order entry can occur directly from the pathway
• Results/status can be reported to the pathway
• Documentation can be performed against orders within the pathway
• Prompts, scheduled activity lists and conditional flags are generated by the system
• Multidisciplinary involvement in the planning process is improved
• Integrated views of information improve decision making

Before automating the process it is essential to define the demands for information within multiple care settings and those that support the linkages between care settings. Access to an automated system is essential for maintaining continuity of patient care information across the continuum.[4] The next stage of pathway development involves the analysis of current clinical practice. Analysis of aggregated patient data is essential to minimize sampling error and ensure statistical validity. While individual patient data is the input, the focus needs to be on the global results of processes rather than focusing on individual patient outcomes. To observe any significant improvements in quality, efficiency and cost-effectiveness, process re-engineering must be directed at the population level. In the absence of an automated process, data acquisition can be tedious and analysis time-consuming.

8.2.1 Data Acquisition at the Point of Care

Acquiring data from the point of care delivery is the most efficient method of defining current practice. Capturing the data from its original source wherever possible is critical, whoever that source may be, whether a physician, nurse, other healthcare provider, patient/family, physiologic monitor or other bedside device. Data acquired from the point of care can be stored for later abstraction, summarization and aggregation on a cross-patient basis. The data can then be further sorted to help answer the compelling question: *Which interventions delivered in what sequence achieve the best clinical and fiscal outcomes?*

Charting-by-exception is a common methodology employed to reduce the need for care documentation whereby documentation of only nonstandard items is required. Using this method, an absence of documentation implies that the patient's presentation was within normal limits, orders and interventions were carried out according to the standard, and outcomes were met as predicted. Charting-by-exception has not always been favorably received by the risk management and legal community. Without adequate documentation of care that was actually carried out and the associated patient responses, it is sometimes difficult to retrospectively recreate an actual patient scenario.

Automating patient care documentation expedites data entry and enables a legally more acceptable approach to charting-by-exception. Through the automated process, care providers can be presented with the enterprise-defined normal values for an assessment finding or intervention response, or be permitted to pull over the values that were last entered in the event that nothing has changed. This approach to charting-by-exception provides a more complete record and a better audit trail as to what actually occurred while streamlining the data entry process.

8.2.2 Infusion of Scientific Evidence

Once current practice is defined for a given diagnostic category or patient population, review of current research is necessary to validate the clinical appropriateness of the model. Without the incorporation of scientific evidence, pathways can be purely anecdotal. Current practice could also be correlated with accepted national standards or other benchmark data. Benchmarking allows the comparison of practices and outcomes to those in another service or enterprise which have resulted in improved outcomes and best performance.[5] Ultimately, a "best" practice pathway is built to guide the management of individual patients within a patient population. As with any quality improvement effort, the development and implementation of pathways is an ongoing process involving a continuous analysis of variances, ongoing consideration of new scientific evidence, and refinement of pathways to meet cost and outcome goals.

8.2.3 Resource Utilization

"The clinical pathway can be used as a cost and resource allocation tool; the resolution of problems as evidenced by the achievement of goals and expected outcomes tells you whether it's working and the variance analysis tools provide the foundation

for your quality improvement database."[3] A variety of tools for estimating resource utilization, sometimes referred to as patient acuity or classification systems, are currently available. Calculation of scores using these tools, however, is commonly performed retrospectively and often duplicates the documentation of patient care. Therefore, the results are not always an accurate reflection of the actual care delivered. Ideally, calculation of resource consumption should be a concurrent process whereby the score is automatically derived from documentation of the care provided. The concurrent approach eliminates duplication of effort and improves the accuracy and validity of the value obtained. Standard or average resource consumption per pathway can support forecasting of resource requirements. Analysis of variances in resource consumption and associated patient outcomes by pathway may facilitate refinement of the pathway to optimize the cost-effectiveness of care.

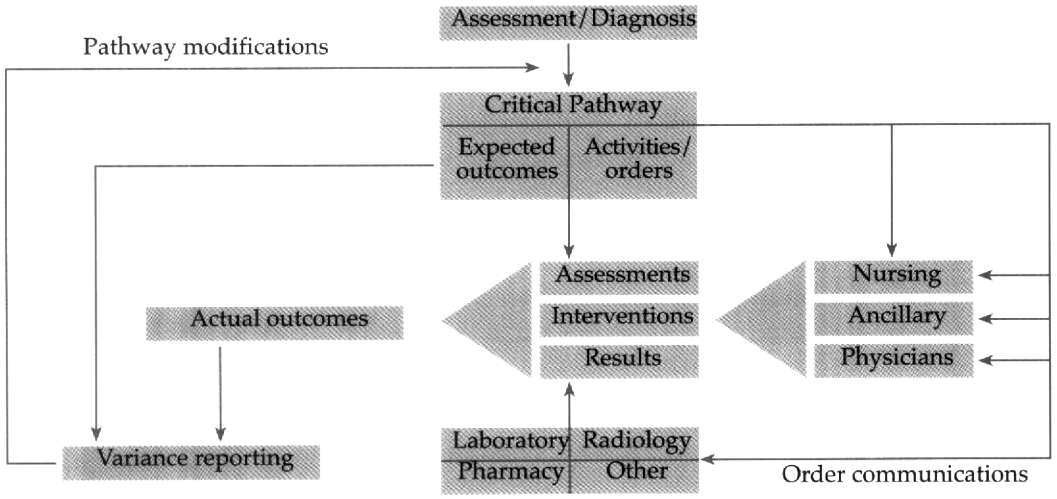
8.2.4 Costs of Care

To ensure success in contract negotiation, healthcare enterprises must implement better mechanisms of determining the actual costs of delivering care for specific diagnoses, procedures and/or pathways. Traditional systems have used patient charges to estimate costs of care. It is well known that charges do not equal costs. With the onset of capitation (i.e., negotiation of a fixed price per covered life), charges are of little value and the need to collect the true costs of care escalates. Similar to resource utilization, costs of care can be extracted by the system in a concurrent manner based on care documented, the salary level of the care provider, and the cost of any associated supplies. By costing out the pathway, some enterprises have been able to offer a fixed price product for certain diagnostic categories.[2] Automated clinical pathways have been shown to decrease length of stay by up to 25%,[2] control hospital costs,[2] and reduce inpatient Medicare losses by more than 50%.[6]

8.3 *Implementing Clinical Pathways*

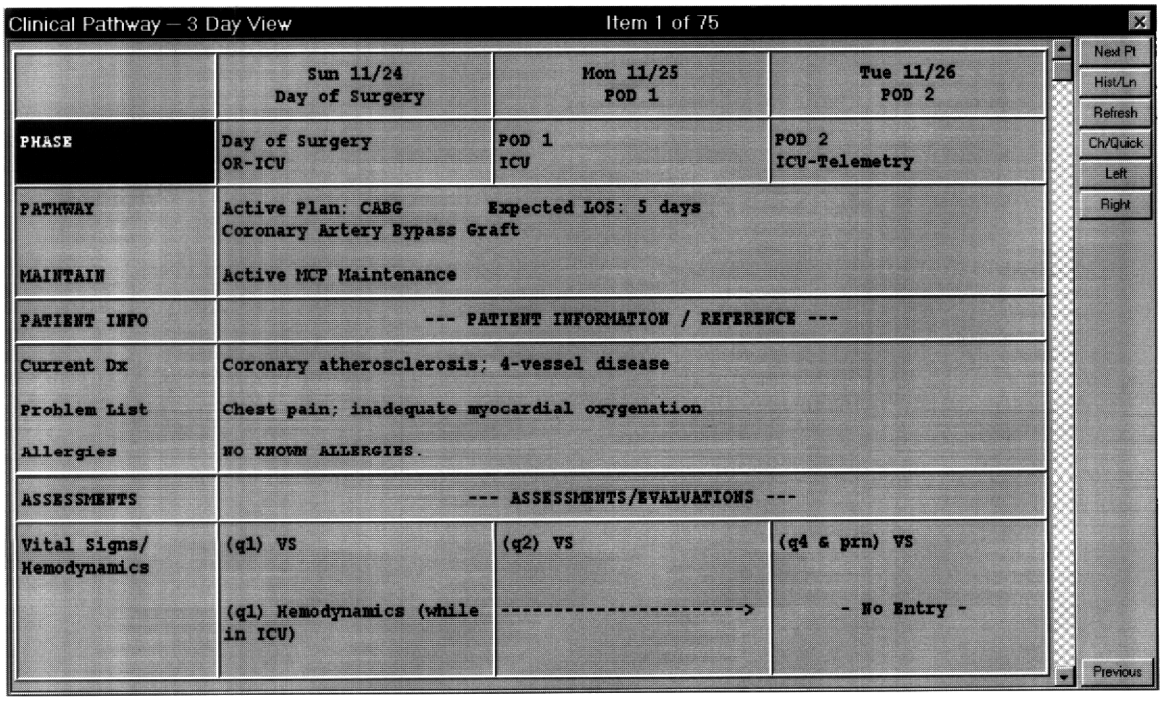
Multidisciplinary involvement in the development of pathways is essential to the successful incorporation of pathways into the overall care process. With the availability of interactive pathways, the pathway becomes a working tool to guide the care of a particular patient. The overall flow of an automated pathway is illustrated in Figure 8.1. Upon entry of an assessment finding or diagnosis, the care provider can be presented with a list of pathway options. In addition, a patient may meet specific criteria or fall into certain risk groups for which an automated system can provide alerts or conditional branching of the pathway to accommodate such characteristics. Incorporating rules-based logic into pathways expedites the process of customizing a given pathway to meet the unique needs of the patient.

Figure 8.1 – Automated pathway flow diagram.



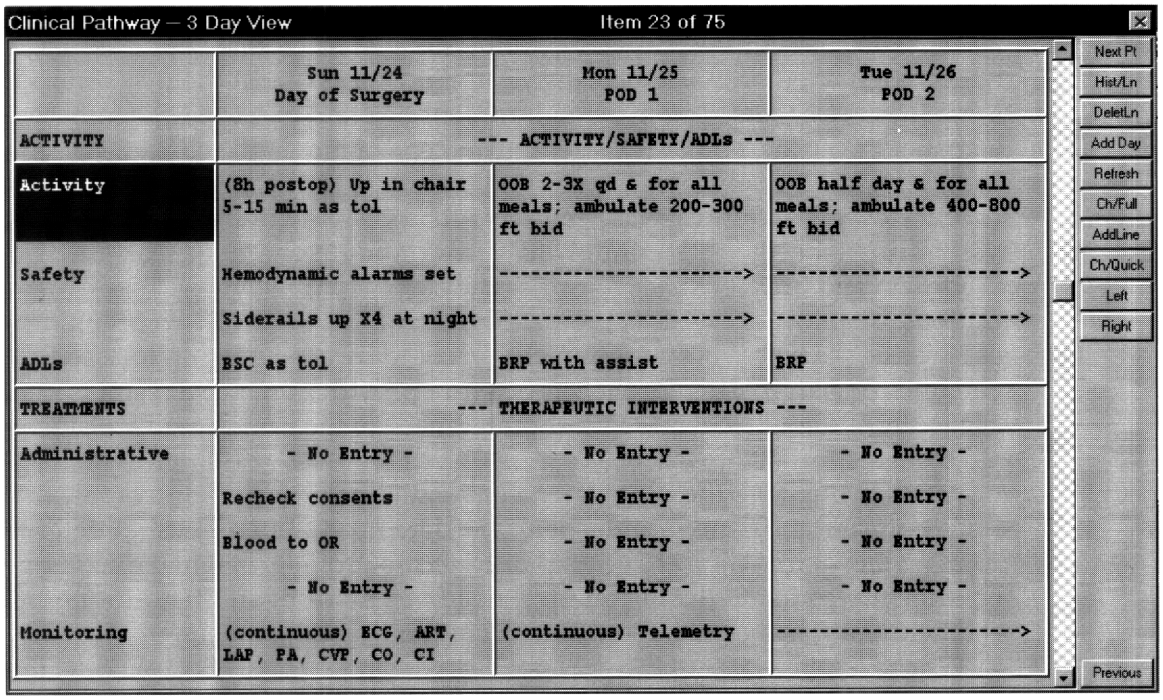
A clinical pathway is typically laid out with an element of time across the horizontal axis and aspects of care and expected outcomes along the vertical axis (see Figure 8.2a-8.2c). Aspects of care may include physician orders, nursing interventions, ancillary services, and consultations.

Figure 8.2(a) – Sample automated pathway: patient information.



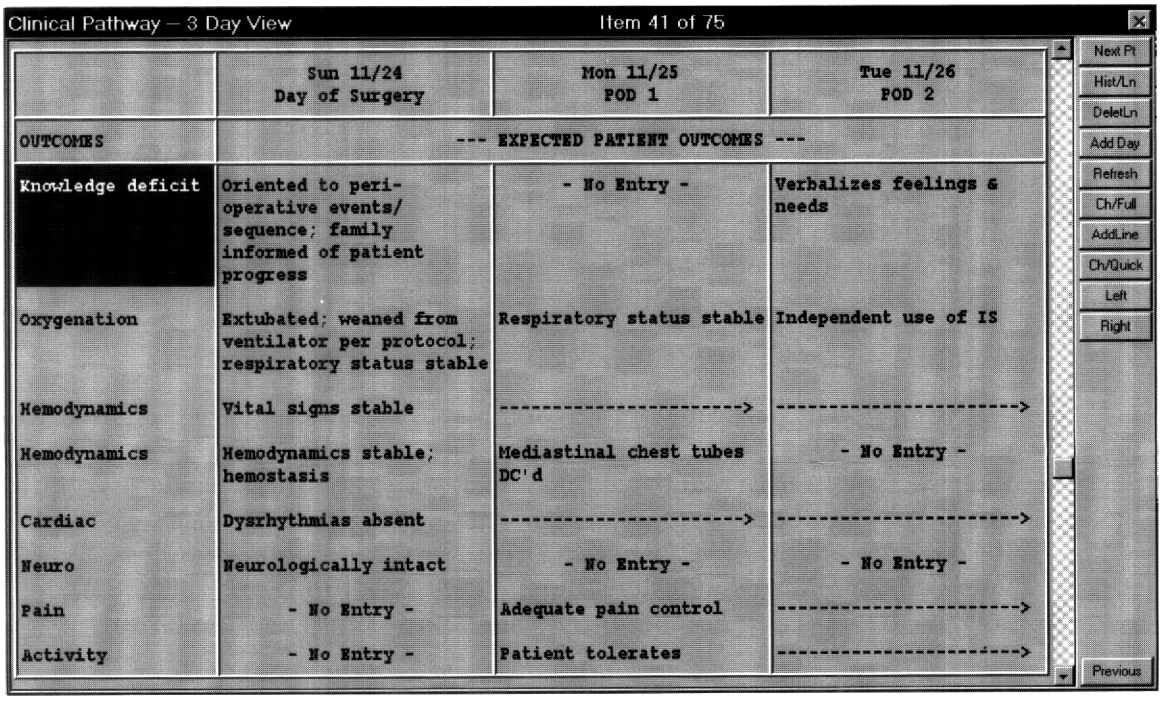
	Sun 11/24 Day of Surgery	Mon 11/25 POD 1	Tue 11/26 POD 2
PHASE	Day of Surgery OR-ICU	POD 1 ICU	POD 2 ICU-Telemetry
PATHWAY	Active Plan: CABG Coronary Artery Bypass Graft	Expected LOS: 5 days	
MAINTAIN	Active MCP Maintenance		
PATIENT INFO	--- PATIENT INFORMATION / REFERENCE ---		
Current Dx	Coronary atherosclerosis; 4-vessel disease		
Problem List	Chest pain; inadequate myocardial oxygenation		
Allergies	NO KNOWN ALLERGIES.		
ASSESSMENTS	--- ASSESSMENTS/EVALUATIONS ---		
Vital Signs/ Hemodynamics	(q1) VS	(q2) VS	(q4 & prn) VS
	(q1) Hemodynamics (while in ICU)	---------->	- No Entry -

Figure 8.2(b) – Sample automated pathway: aspects of care.



	Sun 11/24 Day of Surgery	Mon 11/25 POD 1	Tue 11/26 POD 2
ACTIVITY	--- ACTIVITY/SAFETY/ADLs ---		
Activity	(8h postop) Up in chair 5-15 min as tol	OOB 2-3X qd & for all meals; ambulate 200-300 ft bid	OOB half day & for all meals; ambulate 400-800 ft bid
Safety	Hemodynamic alarms set	----->	----->
	Siderails up X4 at night	----->	----->
ADLs	BSC as tol	BRP with assist	BRP
TREATMENTS	--- THERAPEUTIC INTERVENTIONS ---		
Administrative	- No Entry -	- No Entry -	- No Entry -
	Recheck consents	- No Entry -	- No Entry -
	Blood to OR	- No Entry -	- No Entry -
	- No Entry -	- No Entry -	- No Entry -
Monitoring	(continuous) ECG, ART, LAP, PA, CVP, CO, CI	(continuous) Telemetry	----->

Figure 8.2(c) – Sample automated pathway: expected outcomes.



	Sun 11/24 Day of Surgery	Mon 11/25 POD 1	Tue 11/26 POD 2
OUTCOMES	--- EXPECTED PATIENT OUTCOMES ---		
Knowledge deficit	Oriented to peri-operative events/ sequence; family informed of patient progress	- No Entry -	Verbalizes feelings & needs
Oxygenation	Extubated; weaned from ventilator per protocol; respiratory status stable	Respiratory status stable	Independent use of IS
Hemodynamics	Vital signs stable	----->	----->
Hemodynamics	Hemodynamics stable; hemostasis	Mediastinal chest tubes DC'd	- No Entry -
Cardiac	Dysrhythmias absent	----->	----->
Neuro	Neurologically intact	- No Entry -	- No Entry -
Pain	- No Entry -	Adequate pain control	----->
Activity	- No Entry -	Patient tolerates	----->

Automating pathways permits varying views based on care provider role and privilege level. Higher level views of the pathway may be provided to physicians and case managers, for example, while comprehensive views may be provided to direct care providers. Discipline-specific views streamline the display to include only the salient aspects of the pathway required by that discipline. For example, physical therapists may be primarily interested in viewing physical therapy orders, occupational therapy orders, and nursing interventions and expected outcomes related to the patient's physical mobility, strength and endurance, and self-care status. In some cases, physical therapists may want to have access to the medication administration record to view when the last pain medication was delivered. An automated system must be flexible enough to accommodate the needs of all disciplines.

Orders and activities that comprise the clinical pathway (e.g., assessments, interventions, diagnostic tests, treatments, etc.) can be electronically communicated to the responsible parties. This communication could include posting to associated work schedules or activity lists for the various care providers. Once a result is made available to the system, it can be communicated back to the care provider or incorporated into the appropriate flowsheet as specified by the healthcare enterprise.

When evaluating the patient's achievement of expected outcomes, the system should present the care provider with the data needed to make that determination. Upon review of this clinical information, the care provider can make a judgment as to whether the outcome has been met, needs to be re-evaluated at a later date, or whether the substance of the outcome itself requires adjustment.

Whenever an aspect of care has not been documented and is past due, the system can generate a flag alerting the care provider that it is overdue. When the overdue conflict is resolved, the care provider can be prompted to document whether there was a variance to the standard pathway and the associated rationale for the variance. Similarly, variances can be documented against outcomes that are not met according to the timeframe specified in the standard pathway.

8.4 Decision Support

A key value to the automation of clinical information is to facilitate the assimilation of data to enhance fast, effective decisions. Decision support can range from alerts, prompts and reminders, to complex rules-based algorithms and clinical protocols. "Unaided humans are not capable of providing the persistent commitment to detail and to decision making logic (rules) necessary to effect standardization of care comparable to that achieved by an executable computerized protocol."[7]

8.4.1 Alerts, Prompts and Reminders

Alerts may be incorporated into an automated system to notify the care provider of a critical event which has relevance to the current function. Flagging of clinical values that are out-of-range and those that are critically abnormal expedites notification of potentially significant changes in a patient's condition. Prompts may be used to guide the care provider through the data entry process to ensure complete, consistent and valid information. Reminders may include conditions and recommended actions such as the most recent laboratory test result that has bearing on a new order, sug-

gested supplemental orders such as assessment of kidney function when ordering nephrotoxic antibiotics, or contraindications to orders based on the patient's condition or existing therapies and prompts for suggested alternatives.[8]

8.4.2 Treatment Algorithms

An algorithm can be considered a decision tree with a series of yes/no questions with branching logic which serves to guide diagnosis and patient management. When automating algorithms, it is essential to eliminate all ambiguity from the decision steps and rules to ensure universal application. As defined by the Agency for Healthcare Policy and Research,[9] algorithms have the following advantages:

- Result in faster learning, higher retention, and better compliance with established practice standards
- Provide structure for retrospective quality review activities
- Identify situations in which testing is unnecessary
- Permit the testing required to explore the impacts of changing assumptions about outcomes, costs, and preferences on the structure and content of clinical guidelines

8.4.3 Clinical Protocols

Clinical protocols are defined as a series of care requirements for a particular treatment or therapy. Common in the critical care and emergency environments, protocols often include rules that support decisions such as ventilator weaning, anticoagulation management, or acute asthma treatment. Similar to clinical pathways, protocols are generally built based on aggregated data of patient responses and associated interventions that result in optimal outcomes.

Clinical protocols can be considered mini-pathways in themselves or can be incorporated as part of a larger protocol associated with the interventions that apply based on the specific patient's presentation. For example, a pneumonia pathway may have an inherent branch that accounts for temperature status (i.e., normothermic or hyperthermic). The protocol rules may define a set of interventions that apply when the patient's body temperature rises above 102° F, in which case the care provider could be presented with the hyperthermic branch of the pneumonia pathway. All relevant orders could be automatically sent to the associated departments, posted to the requisite work lists, and all relevant documentation screens made available. In this manner, the care provider is guided through the standard for "best" practice, enhancing compliance to the standard.

8.4.4 Managing Complex Disease States and Comorbidities

In today's healthcare climate, patients present in very acute states, often with multiple comorbidities–the care for which may constitute a pathway in itself. Without automation, customizing the pathway to the individual patient and merging relevant pathways can be an overwhelming task. Using an automated method not only facilitates the building of standard pathways, but allows for the ongoing customization of the pathway for the individual patient and merging of multiple pathways and protocols as the patient's condition warrants (see Case Scenario).

Case Scenario

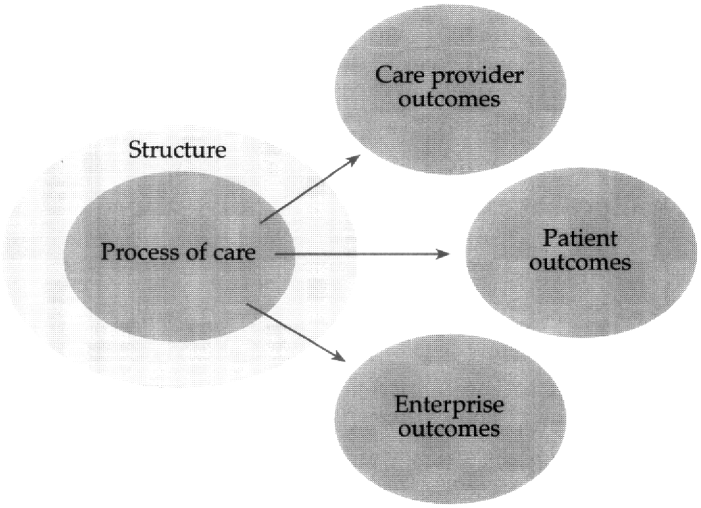
A patient with degenerative joint disease may be scheduled for a total hip arthroplasty. The enterprise has developed a standard pathway for total hip arthroplasty. However, this patient also has chronic diabetes mellitus. Due to the large volume of diabetic patients seen at the enterprise, a standard hybrid pathway for total hip arthroplasty with chronic diabetes mellitus was developed and selected for this patient. Postoperatively, the patient experiences a myocardial infarction necessitating the suspension of the majority of the total hip arthroplasty orders and interventions and initiation of the acute myocardial infarction pathway. The system presents the care provider with the orders, interventions and expected outcomes related to the total hip arthroplasty for possible suspension or alteration. The care provider is prompted to provide rationale for the variances. The pathway aspects related to diabetes may be continued as originally planned or adjusted as necessary based on the patient's current condition. When adding the myocardial infarction pathway, the system can automatically screen for conflicts or overlaps between the existing orders and interventions. Based on an enterprise's definitions, the system can be configured to resolve obvious conflicts between pathways and present the care provider with questionable conflicts. Aspects of the total hip pathway can be resumed as appropriate.

8.5 Outcomes Measurement

Successful implementation of an effective case management program is dependent upon the development of reliable tools to measure patient care outcomes[1] and to analyze variances and update pathways in current use.[3] Most quality management efforts today focus on outcomes improvement, both clinical and fiscal. Using data to ensure the deployment of cost-effective processes involves knowing what works (efficacy), using what works (appropriateness), doing well what works (execution), and considering the values that underlie these processes (purpose).[10] "All four areas must be pursued effectively if healthcare quality is to be successfully defined, measured, and protected."[11]

The relationship between structure, process and outcome is shown in Figure 8.3. The process of care is carried out within a structure that influences access and delivery. The result of the care process is outcomes. Outcomes can be divided into patient outcomes, care provider outcomes and healthcare enterprise outcomes.

Figure 8.3 – Quality improvement targets in the healthcare enterprise.



8.5.1 Patient Outcomes

Indicators of patient outcome include mortality rate, complications, patient satisfaction and improved quality of life as evidenced by increased longevity and improved functional capacity (e.g., self-care abilities, symptom management, health-promoting behaviors). Morbidity and mortality rates are the most commonly measured indicators of patient outcome. However, measurement of patient satisfaction is gaining emphasis. Measurement of functional capacity pre- and post-treatment is essential to determine whether the healthcare process did the patient any good. Questions that need to be addressed include: Is the patient any better off as a result of this healthcare experience? Is the quality of life improved, maintained or declined? Is the patient able to care for himself, manage his own symptoms and demonstrate health-promoting behaviors? Outcome models such as the Medical Outcomes Study 36-Item Short Form (SF-36) and the Functional Independence Measure (FIM) are commonly used to measure patient functionality at various stages throughout their disease management and recovery to determine the value of the care received. Using standard outcomes measurements facilitates accurate comparison between practitioners and with other institutions. Global measures of outcomes assessment do not replace the need for clear definitions and measurement of the patient's response to treatment, taking into account the severity of illness and the presence of comorbidities.[12]

Pathways are not always designed to focus on the outcomes of the care delivered (i.e., the patient's response), but rather on the documentation of what the care provider did. From a quality perspective, it is most important to consider both perspectives, i.e., the documentation of what the patient learned in addition to what content was taught. When designed from a patient outcome perspective, the evaluation of progress along the pathway becomes a verification of outcomes.[13]

8.5.2 Care Provider Outcomes

Care provider outcomes include increased satisfaction with the care delivered, autonomy in practice, participation in decision making, and reduced turnover. Studies have shown that positive care provider outcomes lead to better patient outcomes. In a study of nine critical care units, improved patient outcomes (as evidenced by reduced risk-adjusted mortality) were demonstrated in units with: 1) a patient-centered culture, 2) strong medical and nursing leadership as evidenced by shared visions, supportive visible leaders, and a collaborative approach to problem solving, and 3) effective communication and empowered nursing staff.[14]

8.5.3 Healthcare Enterprise Outcomes

Outcomes related to the healthcare enterprise are primarily related to length of stay and costs. Extended lengths of stay are commonly correlated with increased cost; however, some studies show that the majority of costs can be incurred within the first few days of a patient's stay. Other costs of interest include those associated with personnel, operating expenses and supplies. Today, the most significant enterprise outcome may be the successful, profitable negotiation of managed care contracts.

8.6 *Analyzing the Care Process*

Analysis of pathways, variances and outcomes on a cross-patient basis helps answer critical questions facing healthcare providers today, such as what is the effectiveness of particular interventions or pathways on outcomes, what are the costs of care associated with a particular pathway or intervention, what is the frequency of use of a particular pathway? In analyzing healthcare-related data, individual patient data is the input, but analysis must occur at the aggregate level.

To ensure accurate comparisons of data across populations, it is critical that the patient's data be risk-adjusted. If a particular care protocol treats patients with a higher severity of illness than those to whom they are being compared, the data may be skewed if not risk-adjusted. Several standard scoring mechanisms are currently available, the data to compute those scores can, for the most part, be automatically derived from the patient care documentation.

Measurement of clinical practice and outcomes has been impeded by the lack of standards in terminology related to patient care delivery (i.e., assessment findings, interventions and outcomes). Nomenclature is inconsistent within and among disciplines, thus making it difficult to quantify current practices and benchmark optimal care. To support maximal data integration, terminology needs to be truly multidisciplinary. This may require substantial give-and-take from all disciplines, but the process is essential to the success of data retrieval and comparison. See Table 8.3 for a listing of current standards efforts.

Table 8.3 – Current standards efforts.

Standard and Sponsor	Type of Standard
Nursing Minimum Data Set[15]	Patient demographics, patient responses, interventions, patient outcomes, resource consumption/nursing intensity
North American Nursing Diagnosis Association (NANDA)[16]	Nursing diagnosis by human response patterns
Nursing Intervention Classification (NIC): Iowa Interventions Project[17]	Nursing interventions, patient outcomes
Omaha Community Health System[18]	Nursing diagnoses, problem classification scheme, interventions, patient outcomes
Home Health Care Classification[19]	Nursing diagnoses, interventions, discharge status
Nursing Intervention Lexicon and Taxonomy[20]	Nursing interventions in community health
National Library of Medicine (NLM)[21]	Unified Medical Language System, Unified Nursing Language System (proposed)
International Classification of Disease - Clinical Modification (ICD9-CM)[22]	Diseases, factors influencing health status, external causes of injury, diagnostic and therapeutic procedures
Diagnostic and Statistical Manual of Mental Disorders (DSM-III-R)[23]	Mental disorders
Systemized Nomenclature of Medicine (SNOMED III)	Patient findings (anatomic and morphologic references, living organisms, signs and symptoms, nursing diagnoses, medical diagnoses, administrative, therapeutic, diagnostic and nursing procedures, social conditions)
Physicians Current Procedural Terminology (CPT)[24]	Procedures by service performed by physicians
International Classification of Clinical Services (ICCS)[25]	Procedures (limited domain, greater specificity than SNOMED III)
Laboratory Observation Identifier Names and Codes (LOINC)[26]	Names and codes for laboratory test results
National Council for Prescription Drug Programs (NCPDP) - National Drug Code (NDC)	Medications
World Health Organization (WHO) Drug Codes	Medications (more extensive than NDC)

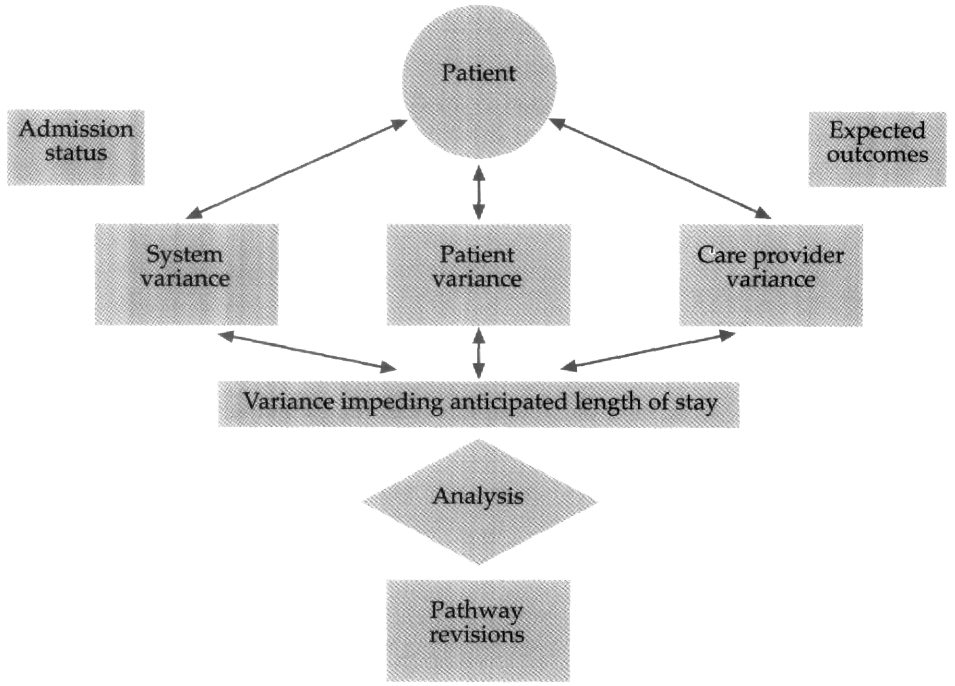
Analysis of the care process occurs on two levels: 1) for the individual patient and 2) on a cross-patient basis. Variances can be defined as discrepancies between planned and actual events, outcomes that differ from anticipated, or deviations from the projected time line. Analysis of variance on an individual patient basis helps fine-tune the patient care process to meet the needs of that patient. Cross-patient analysis of variance facilitates measurement of process effectiveness in achieving desired outcomes. Analysis of aggregated patient data is essential to refine standardized pathways, to risk-adjust data, and to benchmark against regional or national norms. Based on identified variances, particularly those that may be outcome-bearing, care may need to be adjusted for an individual in order to get the patient back on track. From a cross-patient basis, variances must be analyzed to determine if changes should be made to the standard pathway to make it more realistic.

Variances are commonly classified into those attributable to the patient, the care provider and the healthcare enterprise (see Table 8.4). Variances attributable to the patient are further critiqued to see if such variations are consistent enough across the patient population to justify the need to change the standard pathway. Care provider variances may be critiqued to determine if performance problems exist, if resources were insufficient to provide the care as defined by the standard pathway, or if there has been sufficient deviation from the standard based on individual care provider preferences to warrant changing the standard pathway. Variances related to the healthcare enterprise are critiqued to determine if barriers exist within the system that prevent patients from progressing according to the standard. A model for variance analysis is shown in Figure 8.4.

Table 8.4 – Variance categories.

• Inability to learn skill needed for self-care at home • Inadequate social support or systems at home • Not indicated at this time for patient/family • Unable to return to pre-admission environment • Patient/family decision • Complication or condition (physiological/psychological) • Patient condition warrants early discontinuance • Patient noncompliance • Patient/family unavailability • Other _____	• Lack of or inadequate documentation • Physician response time • Other provider response time • Physician/provider error • Time orders were written • Orders outside clinical pathway parameters • Treatment or medication omitted • Not ordered by physician(s)/ physician preference • Other _____	• Bed availability • Schedule conflict • Consultant unavailable • OR time unavailable • Results/data unavailable • Supply/equipment unavailable • Department closed • Placement unavailable • Home health unavailable • Pending payer approval • Other _____

Figure 8.4 – Variance analysis model.



Refinements to pathways can also be tested using a cross-patient analytic tool. A study group of patients may be assigned to a test pathway. Variances and outcomes experienced as a result of the test pathway can be compared to those observed in patients on the existing standard pathway for the same diagnosis. Such analyses can validate the effectiveness of the test pathway and provide evidence to support its substitution for the existing standard.

The value in developing standardized pathways is twofold: 1) to guide the care for the 80% of the cases that fall within the normal range, and 2) to facilitate early detection of variance from the standard and rapid intervention to get the patient back on track.[12] Analysis of variances is primarily useful to consider which variations in interventions contribute, either positively or negatively, to the patient's achievement of outcomes as predicted.

Variance trends can provide useful information for the quality improvement plan. A clinical practice may target certain quality indicators for attention based on those identified in their variation analysis. Any patients that meet the criteria for any of the identified quality indicators may trigger a flag so that care may be guided to eliminate or minimize the impact of that indicator.[1]

8.7 Conclusions

Adoption of managed care has necessitated a change in the way we think about bringing care and services to the patient. Focusing on improving the quality and standardization of care has been shown to reduce costs and enhance patient satisfaction. Data is essential at an aggregate level to evaluate current processes for opportunities to improve both clinical outcomes and costs and to make population-based decisions. Automated, integrated clinical information solutions that incorporate multi-disciplinary clinical pathways have been shown to efficiently and effectively guide clinical practice toward the achievement of desired patient outcomes.

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9.0 IMPROVING THE PROCESS OF CARE

by: Victor Friedman, MS

9.1 *The Process of Care*

From a manager's perspective, the overall process of care in a critical care unit can be described in its simplest form as follows:

- Patients are selected for admission to the unit using a triage process (formal or informal). This is the input to the process of care.
- Over the course of a patient's stay in the unit, various interventions occur which affect the health status of the patient, cost of care, and other factors. This is the process of care.
- Patients are discharged from the unit based on a review process that indicates critical care is no longer appropriate (improved health, death, care is futile, etc.). As a result of their stay in the unit, many factors such as health status, cost of care, and overall satisfaction were changed. This is the output or outcome of the process of care.

Critical care managers need to be more concerned with improving this overall process of care than improving individual therapies. Improving the overall process of care is concerned with assessing and improving the outcomes from combinations of these therapies. First, the outcomes of the process as it currently exists must be measured and a definition of quality must be developed. Second, the process itself is analyzed and clarified to understand the causes of variation in patient outcomes. Finally, this knowledge of cause and effect is used to implement process changes resulting in improved outcomes.

9.2 Key Quality Characteristics (KQCs)

The first task in process improvement is measuring the current status of the process; in this case, the quality of the process of care as it is currently delivered. The question to be asked is, How can you measure the quality of care in the intensive care unit?

There are numerous methods to measure the quality of the process of care. Many are subjective or intuitive measures; therefore, cause and effect analysis is nearly impossible. Some of the quantitative methods include length of stay, severity of illness scoring, mortality statistics, cost measures, outcome measurement models, etc.

In critical care, as in most of healthcare, the process of providing patient care is multidisciplinary, involving physicians, nurses, respiratory therapists, pharmacists, and a long line of other professionals and staff in the hospital. The process of choosing which quality measures to use must also be multidisciplinary and collaborative. It must reflect the varied quality perspectives and expectations of both the care team and the customers of the unit, including not only patients and care givers, but also representatives of finance, administration, and the community.

Vital signs (blood pressure, pulse, temperature), laboratory results, and other indicators are used to quickly and effectively assess and monitor changes in the health status of patients. Similarly, a manageable number of well defined, quantitative measures that accurately reflect the status of the overall process of care need to be defined and developed by the multidisciplinary care team. These measures must be understood and accepted by the members of the care team. They are the "vital signs" of the process of care—the Key Quality Characteristics (KQCs) for the unit.

Group process tools such as brainstorming can be used to assist the interested parties in developing a consensus list of KQCs for the unit. It is important that this preliminary list be revised as the process of care is analyzed and knowledge of the process, its outcomes, and the needs of the customers change.

9.3 Key Process Variables (KPVs)

The KQCs of a process cannot be manipulated directly to improve the process. Consider, for example, length of stay (LOS), a frequently identified KQC. The LOS cannot be lowered directly; rather, the parts of the care process which can be manipulated must be identified and manipulated, resulting in a lower LOS. The variables which can be manipulated to change a KQC are called Key Process Variables (KPVs).

Again, the identification of KPVs is best done in a multidisciplinary group involved directly in the process of care using brainstorming and other nominal group process methods. As the group defines the KQCs of the care process, they should also

define the interventions and therapies, that is, the KPVs, which can be manipulated to cause a change in the process outcomes. The actual cause and effect relationship does not have to be quantified at this time and in fact may only be determined at some later time in the process analysis.

9.4 Variation in Outcomes

It's not surprising that the outcomes for very similar individual patients are often different. These "variations" in outcome are due to many factors. These factors can be classified into four major types of variation:

1. Variation in outcome due to random differences in response of individuals to the same intervention. This is normal population variance.
2. Variation caused directly by a single intervention. This is the traditional "cause and effect" relationship.
3. Variation due to inconsistencies in the process of care. This is the change in outcome resulting from the use of different combinations and timings of interventions over the course of a patient's stay. These are not mistakes, but are usually due to differences in training, personal preference, lack of written policies, etc.
4. Variation due to special causes. These are nonrecurring events which are not a part of the process of care which affect the outcome. Examples are complications, missed treatments, technician errors, medication errors, and mistakes in general.

The variations described in 1 through 3 above are called "Common Cause" or controlled variation. This category of variation is a direct result of the process of care and, therefore, can be controlled by modifying the process. Item 4 represents "Special Cause" or uncontrolled variation. Although not a part of the process of care, these special causes usually have a significant impact on the variation in the outcome of the process.

9.5 Improving the Care Process

9.5.1 Establishing the Database

Limiting data collection to the KQCs and KPVs significantly reduces the size of the data set and greatly simplifies the analysis process. Even so, most units still need a computerized information system to handle the ongoing data collection and analyses required for process improvement. Many units have already implemented text-based systems for documentation of the care process. These systems usually do not allow easy extraction and analysis of process data. On the other hand, database systems do, but significant planning is essential. Only the data required for analysis are entered into the database; those data, moreover, have to be extracted from other systems and coded before they are entered into the database.

The database system for process improvement should be able to:

- Store at least three years of data
- Integrate data from other computerized systems (e.g., laboratory and financial systems) without extensive programming or manual data entry

- Accept automated data entry by scanner or fax to further reduce manual data entry
- Allow additions and deletions from the database without reprogramming
- Provide user access to all the data collected in an integrated fashion
- Provide pre-formatted reports to meet reporting requirements established at the onset
- Include a user friendly report writing system for meeting as yet unidentified data reporting needs

This list is not meant to be a complete set of specifications for a computerized data collection and analysis system. Its purpose is to highlight the need for a system which is efficient from a resource consumption standpoint and flexible to handle the ever changing data which will be required as the process improvement system evolves.

9.5.2 Clarifying and Stabilizing the Process of Care

The process of care is really hundreds or thousands of processes working together. Clarifying and understanding all of these subprocesses is a formidable task. Combined with random variations from "special causes," variations in the way different individuals execute the "same" process can cause the number of real processes to balloon to astronomical numbers. In order to make the analysis manageable, data must be collected on the way care is truly being performed—not on the way it is supposed to be performed. Analysis of these multiple variations in process will then be performed to minimize special causes and establish and evaluate differences in outcomes leading to the definition of a "best current practice".

9.5.3 Collecting Data

Data must be collected on the KPVs and associated KQCs for all patients. The data collection process should do the following:

- Collect data for each process at least daily to accurately reflect the care plan for each patient developed by the multidisciplinary care team
- Review the prior day's care plans and collect data on the actual variations from the original plan and the reasons for those variations
- Collect data on all other complications, mistakes, or "special cause" variations

9.5.4 Analyzing the Data

The first step in clarifying the process is to stratify the data. Stratification is a process of grouping data from patients with similar demographics, diagnoses, age, etc. Groupings are highly subjective and are usually based on the expert knowledge of the multidisciplinary care team. The idea is to analyze the outcomes of multiple variations of the same process applied to an otherwise homogeneous group. Creating these homogeneous test groups minimizes the natural variation in outcomes, making outcome changes due to differences in process easier to detect.

Next, the data concerning special causes and deviations from the care plan should be analyzed. With the use of tools such as pareto charts, runs charts, and correlation and regression analysis, the factors which most impact outcomes can be identified. These items should be the focus early in the process improvement strategy. They impair the ability to effectively improve the care process. Moreover, reducing and eliminating these special causes often lead to significant improvement in process outcomes.

Eliminating special causes still leaves the problem of multiple methods for performing what is supposedly the "same" process. These are not the mistakes that were handled in the previous step; these are the "different means to the same end." Again, analyzing the difference in outcomes for stratified groups of patients is key to developing a "best current method." The most difficult task in improving the overall process of care may be persuading care givers, including physicians, to change from the way they do it now to the "best method." Information from the analyses shared with colleagues can be used as a motivating tool. Although most professionals do not like to be told how to practice, they do react favorably to information and use it to make their own decisions to change to new ways of doing things.

9.5.5 The Formal Improvement Process

Once the current process is stabilized, formal improvement of the process can begin. By this point, there may already be significant improvements in outcomes resulting from process stabilization and the elimination of special causes.

Simply having the knowledge of the current status of the patient care process does not improve the overall process. The challenge is much more complex. Developing the ability to measure the status of the care process is only the first step. The next is building the knowledge base on why the process is performing at the current level. That knowledge can then be used to hypothesize the changes to be made to the process and predict the impact of such changes on the overall outcome.

The results of these "experiments" will be used to refine hypotheses and develop new experiments in a continuous cycle of building knowledge for process improvement. This continuous cycle of hypothesis, experimentation, and the application of new knowledge is exactly the "scientific process" which all clinicians studied and used as a part of their clinical education.

9.6 Model for Process Improvement

The following steps describe a workable model for improving the process of care:

Step 1. Make the obvious improvements.

By this time you have developed significant knowledge of the process. If your care team sees an obvious improvement, make it under the following conditions:

- Everyone involved agrees the improvement is obvious
- The impact of a wrong decision is minimal

- Cost of implementation is low

Step 2. Define opportunities for improvement within your span of control.

Many managers are concerned about changing the care process in areas that they do not control such as pharmacy, food service, and state regulations. It is a waste of time to work on these areas before addressing the process which is in your control. The second alternative is to expand your effective span of control into these areas through multidisciplinary collaboration.

Step 3. Balance the resources available with the value of the expected improvement.

Step 4. Use existing knowledge to hypothesize improvements to the process of care.

Step 5. Design and implement experiments to test the hypotheses - perform management research.

Step 6. Analyze the knowledge gained from the results of the experiments.

Step 7. Implement improvements and institutionalize the changes to the process of care.

Backsliding from improved processes wastes scarce resources. When a change is implemented in practice, implement it in your training and documentation. Continue to monitor the change so that you can tell if the new way has truly become the standard way of doing things.

Step 8. Use the knowledge gained to build new hypotheses.

Step 9. Continue to improve by repeating steps 3 through 8.

The cycle ends when you move on to the next part of the care process because it will return a greater improvement for your efforts than the current area. The following are keys to successful process improvement:

- Develop a definition of quality which is quantifiable and monitor it on an ongoing basis
- Start small and plan for success
- Avoid bureaucracy
- Use a multidisciplinary approach
- Get a good computer system to aid in data collection and analysis
- Understand that process improvement takes an investment in time and resources but can be done at any level
- Continuously build knowledge about your processes and act on that knowledge for process improvement

10.0 TABLE CREDITS

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11.0 ILLUSTRATION CREDITS

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Figure 5.7a

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Figure 5.9a

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Figure 5.13c

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INDEX

N

O

P

Q

R

S

T

U

W

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